UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO:

MSP RECOVERY CLAIMS, SERIES, LLC, a Delaware entity, MSPA CLAIMS 1, LLC, a Florida entity, and MAO-MSO Recovery II LLC,

Plaintiffs,

v.

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, RANBAXY LABORATORIES LIMITED, RANBAXY INC., and RANBAXY PHARMACEUTICALS, INC.

Defendants,
_____/

CLASS ACTION COMPLAINT

JURY TRIAL DEMAND

COMPLAINT

COMES NOW, Plaintiffs, MSP RECOVERY CLAIMS, SERIES LLC, MSPA CLAIMS 1, LLC, and MAO-MSO Recovery II LLC ("Plaintiffs"), with all rights as assigned whereby multiple HMOs, MSOs, and IPAs (Collectively referred to herein as "Plaintiffs' Assignors"), by and through its undersigned counsel, hereby brings this Complaint against Defendants, Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Ranbaxy Laboratories Limited, Ranbaxy Inc., and Ranbaxy Pharmaceuticals, Inc., and state as follows:

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I. INTRODUCTION

1. This case involves the Defendants' anticompetitive scheme to delay the market entry of generic Lipitor, a statin used to lower cholesterol.

2. Warner-Lambert[1] secured a patent for Lipitor in 1987. With subsequent extensions, this patent gave Warner-Lambert over thirteen years of market exclusivity for Lipitor, which it launched in 1997.

3. Typically, the expiration of such a patent would allow for generic drug sales—at prices far below those of the branded drug—to commence. But Warner-Lambert was greedy and was not satisfied with the statutory norm. Seeking to maintain the supracompetitive profits derived from the exclusive sale of Lipitor, the Pfizer defendants[2] ("Pfizer") initiated an unlawful anticompetitive scheme to extend their market exclusivity by delaying the market entry of generic atorvastatin calcium ("generic Lipitor").

4. The Defendants' scheme included, among other things, the following anticompetitive acts:

- Fraudulently obtaining a second, duplicative patent from the United States Patent and Trademark Office ("PTO") and wrongfully listing that patent in the book of Approved Drug Products with Therapeutic Equivalence Evaluations (the "orange Book"), published by the United States Food and Drug Administration ("FDA");
- Engaging in serial sham litigation in connection with the fraudulently obtained patent in order to delay market entry of generic Lipitor;
- Filing a sham citizen petition with the FDA in an effort to stall approval of generic Lipitor;
- Entering an anticompetitive and unlawful reverse payment "pay-for-delay" market allocation agreement, which extended beyond the exclusionary reach of the relevant patents, whereby Pfizer provided substantial unexplained payments and other

[1] Pfizer acquired Warner-Lambert and its patents in 2000.
[2] Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC.

valuable financial inducements to Ranbaxy, a generic manufacturer, in exchange for Ranbaxy's agreement to delay generic competition; and

- Manipulating the regulatory scheme and 180-day first-to-file exclusivity period by thwarting efforts to obtain judicial declarations that Pfizer's patents were invalid, unenforceable, and/or would not be infringed by generic Lipitor formulations, thus avoiding the triggering of Ranbaxy's anticipated 180-day first-to-file marketing exclusivity and sustaining Pfizer's and Ranbaxy's ability to, in concert, bottleneck other generic companies from launching generic Lipitor.

5. With this conduct, Defendants fixed, raised, and stabilized the price of Lipitor and generic Lipitor at supracompetitive levels by unlawfully forestalling generic competition.

6. Defendants' conduct has driven up prescription drugs costs to U.S. consumers, the state and federal governments, and third-party payors in an amount between $10 million and $19 million per day, or roughly $4 billion to $7 billion per year.

Lipitor Patents and Warner-Lambert's Fraud on the PTO

7. In 1987, the PTO granted Warner-Lambert a patent for a racemic mixture[3] that inhibited the production of cholesterol (U.S. Patent No. 4,681,893, the "Original Lipitor Patent" or the "'893 Patent"). With subsequent extensions, this patent expired on March 24, 2010.

8. Two years after receiving the Original Lipitor Patent, Warner-Lambert sought to separately patent atorvastatin, the active ingredient in Lipitor and one of the enantiomers in the racemic mixture that Warner-Lambert had already patented, in an effort to ensure an even longer period of patent-protected exclusivity for the blockbuster drug.

9. Warner-Lambert could only obtain a separate patent for atorvastatin if it had a "surprising" quality. Warner-Lambert's data clearly showed atorvastatin to be utterly ordinary, however, so Warner-Lambert decided to engage in inequitable conduct and deceive the PTO in order to obtain the follow-on patent.

[3] A racemic mixture contain an equal amount of two enantiomers; enantiomers have the same chemical formula but are arranged as mirror images.

10. More specifically, in connection with this follow-on atorvastatin patent application, Warner-Lambert deceptively claimed that the isolated enantiomer atorvastatin was, "surprisingly," ten times more active than the racemic mixture, when one skilled in the art would have expected only a two-fold difference in activity. Warner Lambert knew its assertion to be false. Nevertheless, Warner-Lambert knowingly and purposefully submitted a manipulated, unscientific conglomeration of data points—cherry-picked from over a dozen separate tests performed in different formulations over several years—that falsely supported its bogus contention. Accordingly, Warner-Lambert's support for its follow-on patent lacked any basis in fact. Warner-Lambert knew that if the data were analyzed consistently with sound and reasonable scientific principles, the invention claimed in the follow-on patent would provide only a two-fold increase in activity—the same ordinary increase that was widely expected based on the prior art—and that its claimed invention would therefore not be patentable.

11. Given the duty of candor that patent applicants owe to the PTO, which requires the disclosure of all known information that may adversely affect the patentability of the claimed invention, the PTO, oblivious to Warner-Lambert's deception and inequitable conduct, relied on the corrupted data and issued the duplicative follow-on patent (U.S. Patent Number 5,273,995, the "'995 Enantiomer Patent" or the "'995 Patent" or the "follow-on patent") for the isolated enantiomer.

Sham Patent Infringement Litigation and Sham Citizen Petition

12. Driven by the massive profits that Pfizer reaped each day that Lipitor maintained its market exclusivity, and armed with the duplicative follow-on patent, which it knew was invalid and/or unenforceable, Pfizer prosecuted sham patent infringement litigation with the sole purpose of delaying market entry of generic Lipitor.

13. In particular, in early 2003, Pfizer initiated patent infringement litigation against Ranbaxy, the generic manufacturer that filed the first abbreviated new drug application ("ANDA") seeking to market generic Lipitor. The mere filing of this sham litigation triggered an automatic statutorily-mandated thirty-month delay in the FDA's approval of Ranbaxy's ANDA.

14. On the eve of the thirty-month stay's expiration, Pfizer deployed another anticompetitive tactic to impede the FDA's approval of Ranbaxy's ANDA. On July 28, 2005, Pfizer sent a formal letter to the FDA (which it re-filed as a purported "citizen petition" on November 7, 2005), baselessly challenging the FDA's anticipated approval of Ranbaxy's generic Lipitor ANDA and asserting that the FDA should take into account arguments and information that lacked any regulatory, scientific, medical, or other reasonable relevance to Ranbaxy's application. The substance (or lack thereof) and timing of these submission were intended solely to further delay final FDA approval of Ranbaxy's generic Lipitor ANDA.

The Unlawful Reverse Payment, Market Allocation Agreement

15. In or about June of 2008, Pfizer and Ranbaxy abandoned the adversarial positions they had taken in earlier litigation, in which Ranbaxy had alleged some of the above-described conduct, and entered into an anticompetitive, market-allocating pay-for-delay agreement that allowed Pfizer to prolong its Lipitor monopoly and allocated the market for Lipitor and its generic bioequivalents (sometimes referred to as the "Ranbaxy Delay Agreement" or the "Delay Agreement").

16. To disguise its true anticompetitive purpose, the market-allocating pay-for-delay agreement was entered into under cover of litigation that Pfizer brought against Ranbaxy, ostensibly to enforce two process patents (i.e., patents covering manufacturing processes related to Pfizer's method of making Lipitor). This was the only pending litigation between Ranbaxy

and Pfizer related to Lipitor sales in the United States at the time of the agreement. Ranbaxy had a strong likelihood of prevailing in its process patent litigation with Pfizer. Pfizer's patents were weak and were more likely than not to be held invalid or unenforceable in Pfizer's patent litigation against Ranbaxy.

17. Pursuant to this Pfizer-Ranbaxy agreement allocating the market and delaying generic entry, Pfizer gave substantial financial inducements to Ranbaxy to secure the delay of Ranbaxy's generic atorvastatin calcium product in the United States, including: (a) an enormous market allocation agreement pursuant to which Ranbaxy was given the right to market generic Lipitor in at least eleven foreign markets; and (b) Pfizer's sweetheart agreement to dismiss hundreds of millions of dollars in likely damages against Ranbaxy for a pretextual payment of $1 million, stemming from Ranbaxy's "at risk" launch of a separate generic product (quinapril hydrochloride) in violation of patents Pfizer held on the drug (sold under the brand name "Accupril"). These financial inducements were extraneous to any possible results that Ranbaxy might achieve in any U.S. Lipitor patent dispute that existed, or ever could exist, between Ranbaxy and Pfizer and were far in excess of actual (and any potential) litigation costs.

18. In exchange for the payments by Pfizer, Ranbaxy promised not to: (a) enter the market or compete with Pfizer in the atorvastatin calcium market in the United States until November 30, 2011; (b) relinquish or selectively waive its first-to-file 180-day marketing exclusivity for generic Lipitor in a manner that would permit any other filer of an ANDA to market a generic version of Lipitor in the United States before November 30, 2011 (which had the effect of creating a "bottleneck" that blocked FDA approval of later would-be generics); (c) contest the validity of process patents that Pfizer was misusing to delay the efforts of other

would-be generic entrants; nor (d) further protest Pfizer's application for reissuance of the duplicative follow-on patent that had been declared invalid, in part, by the Federal Circuit.

19. Pfizer also undertook a calculated pattern of sham litigation designed to delay the efforts of other generic manufacturers that sought approval to manufacture and sell generic Lipitor. This anticompetitive behavior involved, among other things, engaging in serial sham litigation concerning the fraudulently-obtained duplicative patent and thwarting any and all efforts to obtain judicial declarations that certain unasserted patents were invalid, unenforceable, and/or would not be infringed by generic Lipitor.

The Obstruction of Later Generic Entrants

20. The Ranbaxy Delay Agreement created a regulatory bottleneck that delayed other, would-be generic entrants from entering the market for atorvastatin calcium. The bottleneck forced other generic ANDA filers to seek judicial determinations regarding all patents ostensibly covering atorvastatin. Only after obtaining appellate determinations that all such patents are invalid and/or non-infringed could Ranbaxy be forced to launch its generic product or lose its180-day exclusivity. If accomplished, generic Lipitor would have entered the market much earlier than November of 2011.

21. But such determinations take time and money, and Pfizer used tactics to prevent later ANDA filers from breaking through the bottleneck. Pfizer opposed early court rulings, delayed proceedings, provided covenants not to sue on unasserted Orange Book-listed patents, and ultimately settled lawsuits brought by other ANDA filers to avoid determinations of invalidity and/or non-infringement.

22. Despite efforts to do so, no ANDA filer was able to circumvent the Ranbaxy Delay Agreement by triggering Ranbaxy's 180-day marketing exclusivity prior to November 30, 2011.

Defendants' Actions Delayed Generic Competition for Many Months

23. This class action complaint seeks damages on behalf of all end-payors in the United States and its territories who indirectly purchased, paid for, and/or provided reimbursement for Lipitor and/or its generic bioequivalents during the period March 24, 2010 through and until the anticompetitive effects of Defendants' conduct cease, and who were injured by Defendants' anticompetitive actions. But for Warner-Lambert's fraud, the PTO would never have issued the follow-on patent—not at any time, not in any form. And but for the fraudulently obtained follow-on patent, sham patent infringement litigation, baseless citizen petition, and unlawful pay- for-delay market allocation agreement, a generic Lipitor equivalent would have been available in the United States far earlier than November 30, 2011. Thus, Defendants' actions prevented the class from purchasing less-expensive Lipitor, and less-expensive generic Lipitor equivalents, for their atorvastatin calcium requirements. Defendants' actions have resulted in a continuing anticompetitive harm and antitrust injury to Plaintiff's Assignors and all members of the Class.

II. THE PARTIES

24. MSP Recovery Claims, Series LLC, is a Delaware entity with its principal place of business located at 5000 S.W. 75th Avenue, Suite 400, Miami, FL 33155.

25. Plaintiff MSPA Claims 1, LLC is a Florida entity, with its principal place of business located at 2600 S. Douglas Rd., Suite 1008, Coral Gables, FL 33134.

26. Plaintiff Mao-MSO Recovery II, LLC, Series PMPI, is a Delaware entity with its principal place of business at 45 Legion Drive, Cresskill, NJ 07626.

27. Plaintiffs have been assigned the rights to recover payments for pharmaceuticals that numerous Medicare Advantage Organizations ("MAOs"), Health Maintenance Organizations ("HMOs"), full risk Maintenance Service Organizations ("MSOs"), and full risk Independent

Physicians Associations ("IPAs"). As a result of these assignments, Plaintiffs are empowered and have standing herein to pursue the claims of its Assignors that purchased Lipitor and generic Lipitor at supracompetitive prices due to the Defendants' conduct.[4]

28. Accordingly, Plaintiffs stand in the shoes of their assignors and are entitled to recover any amounts owed to Plaintiffs' Assignors by nature of Defendants' scheme to artificially inflate the price of Lipitor.

29. Since March 24, 2010, Plaintiffs' Assignors have been paying millions of dollars to purchase Lipitor at supracompetitive prices in every state in the United States, and Plaintiffs' Assignors will continue to have no choice but to continue to purchase monopoly-priced brand Lipitor until the Defendants' illegal market allocation scheme ends.

30. Defendant Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware. Pfizer Inc. has a place of business at 235 East 42nd Street, New York, New York 10017.

31. Defendant Pfizer Ireland Pharmaceuticals is an Irish unlimited liability company with registered offices at Operations Support Group, Ringaskiddy, County Cork, Ireland. Pfizer Ireland Pharmaceuticals is a wholly-owned, indirect subsidiary of Pfizer Inc.

32. Defendant Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. In 1997, Warner-Lambert Company and Pfizer began co-promotion of Lipitor, and in mid-2000, Warner-Lambert Company became a wholly-owned subsidiary of Pfizer Inc. At the end of 2002, Warner-Lambert Company became a Delaware limited liability company and changed its name to Warner-Lambert Company LLC.

[4] Representative claim assignments are attached in the Appendix immediately following this Complaint.

33. Throughout this complaint, Warner-Lambert Company and Warner-Lambert Company LLC are collectively referred to as "Warner-Lambert." The phrase "Warner-Lambert" includes, but is not limited to, Warner-Lambert employees Bruce D. Roth, Joan Thierstein, and Jerry F. Janssen.

34. Defendants Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert are collectively referred to as "Pfizer."

35. Defendant Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, with a place of business located at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India.

36. Defendant Ranbaxy Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business located at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy Inc. is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

37. Defendant Ranbaxy Pharmaceuticals Inc. is a wholly-owned subsidiary of Ranbaxy Inc., with a place of business located at 9431 Florida Mining Boulevard East, Jacksonville, Florida 32257.

38. Defendants Ranbaxy Laboratories Limited, Ranbaxy Inc., and Ranbaxy Pharmaceuticals Inc. are collectively referred to as "Ranbaxy."

39. Defendants' actions, described below, were in furtherance of the alleged wrongdoing and were authorized, ordered, or performed by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

III. JURISDICTION AND VENUE

40. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs, and at least one member of the putative class is a citizen of a state different from that of one of the defendants.

41. Venue is appropriate within this district under 28 U.S.C. § 1391(b) and (c) because Defendants transact business within this district and because the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

IV. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

42. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-392, manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

43. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list in the Orange Book any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents. Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance. 21 U.S.C. §§ 355 (b)(1) & (c)(2). Process patents, by contrast, are ineligible for Orange Book listing.

44. The FDA relies completely on the brand name manufacturer's truthfulness about the patents' validity and applicability, as it does not have the resources or authority to verify independently the manufacturer's patents for accuracy or trustworthiness.

The Hatch-Waxman Amendments

45. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A generic manufacturer seeking approval to sell a generic version of a brand name drug may now file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug—that is, that the generic drug is bioequivalent to the brand name drug. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The FDA assigns an "AB" rating to generic drugs that are bioequivalent to branded drugs.

46. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

47. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical companies' incentives to create new and innovative products.

48. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion, with generic drugs accounting for 75% of prescriptions.

Paragraph IV Certifications

49. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications. A Paragraph IV certification must state "that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product."

50. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of thirty months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval," but it cannot authorize the generic manufacturer to go to market with its product.

51. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV

certification is entitled to a 180-day period of protection from competition with other ANDA filers.[5]

52. The statutory rules in effect for ANDAs filed (and Paragraph IV certifications submitted) before December of 2003 created an opportunity for branded drug companies and first-filed ANDA applicants to collude to delay generic drug competition. Because the running of the first-filer's 180-day exclusivity is not triggered except after (a) the first-filer commercially markets its product, or (b) an appellate court determination that all Orange Book-listed patents for the branded drug are invalid or not infringed, the first-filer can, in concert with the branded drug company, create a "bottleneck" that keeps later-filed ANDA applicants from entering the market simply by deferring commercial launch of (or "parking") its product. The FTC has observed this potential and the anticompetitive effects that can result. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration, An FTC Study, at vi-xi (FTC July 2002).[6]

53. Absent a payment from the branded company, it is generally not in a first-filed ANDA applicant's unilateral economic interests to park its 180-day exclusivity and delay the return on its investment in connection with the filing of its ANDA.

54. By contrast, brand name manufacturers have large financial incentives to (a) delay the first-filer from triggering its 180-day exclusivity and (b) impede subsequent ANDA filers from obtaining a court decision that all Orange Book-listed patents are invalid and or non-infringed, in order to delay generic entry.

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[5] However, the brand name manufacturer or its licensee may sell an "authorized generic" during the first-filer's exclusivity period.

[6] A retroactive clause of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act clarified that the "court decision" exclusivity trigger begins when an invalidity or non-infringement decision is rendered "by a court from which no appeal (other than a petition of the Supreme Court for writ of certiorari) has been or can be taken." Pub. L. No. 108-173 § 1101(b)(3) (2003).

B. The Benefits of Generic Drugs

55. Typically, AB-rated generics cost much less than their branded counterparts and competition from lower-priced generics typically causes a corresponding drop in the price of the branded drug. Over time, as more generic equivalents compete with each other, prices decline even further. A recent study by the FTC found that on average, generics capture 90% of a brand's prescriptions within a year, and generic prices are 85% below the pre-generic brand price. *See* Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010), p. 8.

56. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise). No substitution can occur until a generic manufacturer enters the market, however, which allows the brand name manufacturer to profitably charge supracompetitive prices without a material loss of sales volume. Consequently, brand name drug manufacturers have a strong interest in seeking to delay the market entry of generic competition.

57. There is an incentive to choose a less expensive generic equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generics. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members' prescriptions, whether filled with branded or generic drugs, so they offer their members lower copays for generic drugs in order to encourage the use of generics. Members also

face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

58. Once a generic equivalent hits the market, the generic quickly overtakes sales of the branded drug. More than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. The speed with which generic drugs take over the market appears to be increasing: in a sample of drugs losing patent protection between 1991 and 1993, generics held, on average, a 44% market share after one year; by 2008, generic versions would capture as much as 86% to 97% of the market within the first month of availability.

59. Branded manufacturers are well aware of generics' steady erosion of their previously monopolized market. Branded manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting, as Defendants did here, to any means possible, including unlawful conduct.

C. Brand Manufacturers Have Learned How to Exploit the Hatch-Waxman Regulatory Framework

60. Although the Hatch-Waxman Act was "designed to speed the introduction of low-cost generic drugs to market," drug companies have learned how to exploit certain provisions of the Act in ways that frustrate congressional intent and violate antitrust laws.

61. As Defendants' conduct as set forth herein illustrates, brand name manufacturers may manipulate the FDA regulatory process by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with Paragraph IV certifications (even if the competitor's product does not actually infringe the listed patent(s)) in order to delay final FDA approval of an ANDA for up to thirty months.

62. The first generic applicant oftentimes effectively "parks" its 180-day exclusivity by not commercially marketing the generic drug and by colluding with the brand name

manufacturer to ensure that its patents are not invalidated. Such collusion prevents other ANDA applicants from coming to market.

63. That brand-name manufacturers often sue generics under Hatch-Waxman for the purpose of delaying generic competition—as opposed to enforcing a valid patent that is actually infringed by the generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation, either by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied in a recent study conducted by the Federal Trade Commission (FTC).

64. The economic effect of the monopoly-to-commodity transition upon generic entry motivates unlawful drug company collusion. Typically, in reverse payment agreements, the brand company compensates the would-be generic manufacturer to stay off the market. A generic may make more money accepting cash or other consideration from the brand and agreeing not to compete than it would by pursuing and winning patent litigation or making an "at-risk" launch (even when the risk is minimal or nonexistent). As the United States Supreme Court noted recently, a settlement between a brand company and the first-to-file generic drug company should be viewed with particular scrutiny because it "removes from consideration the most motivated challenger, and the one closest to introducing competition." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2235 (2013).

65. Although the Hatch-Waxman Act includes an exception to the requirement that later ANDA filers must await the first filer's chosen launch date—the logjam is broken when challengers can obtain final court decisions concluding that all Orange Book-listed patents are invalid or not infringed—brand manufacturers have adapted by strategically suing on some, but not all, applicable patents. When they do so, later-filed generics must challenge the non-asserted

patents in what are often lengthy and difficult declaratory judgment actions. The resultant procedural complexity adds more delay and corresponding brand profit.

V. FACTUAL BACKGROUND

A. A Short Primer on Statins

66. Lipitor belongs to a class of drugs called statins. Discovered in the 1970s, statins lower cholesterol by successfully inhibiting the liver enzyme 3-hydroxy 3-methylglutraylcoenzyme A reductase ("HMG-CoA reductase"). HMG-CoA reductase controls the rate at which our bodies produce cholesterol; inhibiting HMG-CoA reductase reduces the production of cholesterol. High levels of cholesterol are thought to cause serious health problems in some populations, including coronary heart disease and atherosclerosis.

67. Efforts to reduce cholesterol levels are a big business: by 1997, five of the largest pharmaceutical companies sold six different brand-name statins. In 2002, almost one in ten Americans aged twenty and older took a statin. In 2004, sales of statins topped $15.5 billion, and comprised 6.6% of all prescription drug sales.

68. Branded statins cost between $2.50 and $5.00 for a single daily pill ($75 to $150 per month, $900-$1,800 per year). Generic statins cost markedly less, sometimes less than $1 per day.

69. Statins consist of three structural parts: a lactone ring, a linkage group (denoted as "X"), and a group or groups connected to the linkage group (referred to herein as an "R group").

70. The R group for the well-known statins can contain one or more single rings or fused rings, along with other substituent groups.

71. In the 1970s, researchers discovered that mevastatin, naturally occurring in red yeast and rice, inhibited cholesterol synthesis.

72. Mevastatin contains a lactone rings, a linkage group, X, and an R group of two fused rings with substituents. One of the fused rings contains a methyl group ($-CH_3$) on the right ring and an additional O-linked substituent group on the left ring.

73. Around the same time, researchers discovered that lovastatin, naturally occurring in red yeast, rice, and oyster mushrooms, was another highly potent HMG-CoA reductase inhibitor. In the early 1980s, Merck sought and gained approval for Mevacor, a brand name version of lovastatin, which became the first statin available in the United States.

74. The structure of lovastatin is very similar to mevastatin. Lovastatin also contains a lactone ring and an R group joined to the lactone ring by a linkage group. Lovastatin's R group is similar to mevastatin's R group but has one additional methyl group.

75. In the early 1980s, Warner-Lambert sought to enter the market by developing a "me-too" version of the already-identified statins. Researchers at Warner-Lambert came up with a formulation that used the same lactone ring as mevastatin and lovastatin but contained different linked substituents as the R group. Warner-Lambert called their new statin "atorvastatin."

B. The Chemistry of Enantiomers

76. Some background on the chemistry of enantiomers is helpful to understand how the Original Lipitor Patent covered the compound that Warner-Lambert sought to patent separately through fraudulent conduct in the PTO.

77. Isomers are two or more compounds with the same chemical formula (that is, containing the same atoms) but different arrangements of atoms. Stereoisomers are isomers in which the same atoms are bonded together, but where the three-dimensional configuration of those atoms differs.

78. Enantiomers are stereoisomers that are mirror images of each other and cannot be superimposed; they have the same atoms, bonded together in the same way, but one is arranged as a reflection of the other. Consider, for example, a left hand and a right hand.

79. Pairs of enantiomers have many identical chemical and physical properties, such as shared melting points, solubility, and colors. Other properties, such as biological properties, may be vastly different.

80. Enzymes, including the cholesterol-producing HMG-CoA reductase, typically display a preference for interacting with one enantiomer over the other. It is common for one enantiomer to have all, or most, of the biological activity. The other enantiomer will have little or no biological activity.

81. Enantiomers can be distinguished from one another by their effect on the rotation of polarized light. Enantiomers reflect polarized light in either a clockwise direction (right, denoted with a "+") or a counter-clockwise direction (left, denoted with a "-"). An unequal mixture of two enantiomers is optically active; the degree of optical rotation reflects the percentage of each enantiomer in the mixture. A racemic mixture or racemate exists when equal mixtures of two opposite enantiomers are present. A racemate is not optically active because the optical rotations of the enantiomers cancel each other.

82. To differentiate enantiomers on paper, each enantiomer is assigned a configuration based on priority rules that rank the atoms or substituent group of atoms that are attached to the compound's chiral center. If the priority proceeds in a clockwise direction, the enantiomer has an "R" (right) configuration; if the arrangement is counter-clockwise, the enantiomer has an "S" (left) configuration.

83. In addition to R/S and +/- configurations, a molecule's configuration can also reference the location of the substituent atoms or groups of atoms relative to each other. An arrangement where both the major substituents lie on the same side of the plane of reference is called a cis arrangement. An arrangement where the major substituents appear on the opposite sides of the plane is called a trans arrangement.

84. The lactone rings found in statins have two chiral centers, one at the carbon atom attached to the hydroxyl group and the other at the carbon atom attached to the linkage group. Rings containing two chiral centers give rise to four possible isomers—the R-cisisomer ("R-cis"), the S-cisisomer ("S-cis"), the R-trans-isomer ("R-trans"), and the S-trans-isomer ("S-trans") – and two enantiomeric pairs—R-cisisomer & S-cisisomer and R-trans-isomer & S-trans-isomer.

85. At the time Warner-Lambert was developing Lipitor, the preferred configuration for the lactone ring in a statin—that is, the configuration offering the highest level of cholesterol inhibition—was the R-trans configuration.[7] Both mevastatin and lovastatin have lactone rings in the R-trans configuration. In the case of HMG-CoA reductase inhibitors, the R-trans enantiomer appeared to be the active enantiomer that inhibited HMG-CoA reductase and reduced the production of cholesterol.

C. Warner-Lambert Obtains the Original Lipitor Patent

86. On March 30, 1986, Warner-Lambert filed U.S. Patent Application No. 868867 for a group of compounds and pharmaceutical compositions useful as hypercholesterolemic and hypolipidemic agents. The patent application was entitled "Trans-6-[2-(3- or 4-Carboxamido-

[7] *See, e.g.*, Alberts, A. *et al.*, *J. Proc. Natl. Acad. Sci. USA* 1980, 77:3957; Stokker, G.E., *et al.*, *J. Med. Chem.* 1985, 28:347-358; Stokker, G.E., *et al.*, *J. Med. Chem.*, 1986, 29:849-852.

Subsituted Pyrrol-1-yl)alkyl]-4-Hydroproxypyran-2-one Inhibitors Of Cholesterol Synthesis." This application eventually resulted in U.S. Patent No. 4,681,893 (the Original Lipitor Patent).[8]

87. This lawsuit alleges that Warner-Lambert intentionally and affirmatively lied to the PTO regarding the material facts that enabled it to procure the follow-on patent as well as a later reissuance of that patent. That fraud included making misrepresentations about the Original Lipitor Patent. To understand that fraud, one must first understand the background, claims, and uses of the Original Lipitor Patent.

The Patent Specification for the Original Lipitor Patent

88. As alleged more fully below, Warner-Lambert stated in the patent specification for the Original Lipitor Patent that "in its broadest aspect the present invention provides compounds of structural formula I."

89. Like other statins, structural formula I contains a lactone ring, a linkage group (X), and an R group.

90. Consistent with conventional thinking at the time, Warner-Lambert's application for the Original Lipitor Patent contemplated the trans-form of compounds in structure formula I, including Warner-Lambert's "me-too" statin, atorvastatin. The application contemplated atorvastatin in a variety of formulations, including calcium salts.

91. Warner-Lambert claimed that the disclosed compounds were "useful as hypocholesterolemic or hypolipidemic agents by virtue of their ability to inhibit the biosynthesis

[8] Dr. Bruce David Roth applied for the '893 Patent. Roth, who is not named as a defendant in this action, was, at all relevant times, a leader of the drug discovery team at Warner-Lambert that developed Lipitor. Roth is the named inventor and patent applicant of both the '893 Patent and the duplicative follow-on patent. Both patents issued to Roth and were assigned to his employer, Warner-Lambert. Warner-Lambert's patent attorneys, including Jerry F. Janssen, prosecuted the application.

of cholesterol through inhibition" of the HMG-CoA reductase enzyme. For support, the specification detailed the biological activity of three compounds as compared to the prior art.

92. Research in the 1980s had demonstrated that statin molecules with open lactose rings were highly potent cholesterol synthesis inhibitors—often more potent than the closed lactone ring forms of the same molecules. Warner-Lambert claimed that the invention contemplated the hydroxyl acids, or structural formula I with an open lactone ring:

> Also contemplated as falling within the scope of the present invention are the hydroxyl acids, and pharmaceutically acceptable salts thereof, derived from the opening of the lactone ring of the compounds of structural formula I above.

93. Importantly, Warner-Lambert's '893 Patent application specifies and covers a compound in which the R-trans enantiomer is isolated:

> The compounds of structural formula I above possess two asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran-2-one ring where the alkylpyrrole group is attached. This asymmetry gives rise to four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and Strans-isomers. This invention contemplates only the trans- form of the compounds formula I above.

94. Neither Warner-Lambert nor Pfizer has ever disputed that the patent coverage of the Original Lipitor Patent for atorvastatin calcium included versions in which the R-trans enantiomer is isolated. As the inventor of Lipitor testified, the compounds disclosed in the '893 application and covered by the Original Lipitor Patent were not limited to any particular stereochemistry: "this one structure is meant to represent four different stereo isomers" (that is, the R-trans, S-trans, R-cis, and S-cis isomers of atorvastatin acid).

The PTO Issues the Original Lipitor Patent

95. On July 21, 1987, the PTO issued the '893 Original Lipitor Patent. In the absence of any extensions, the Original Lipitor Patent would have expired on May 30, 2006, twenty years

from the date of the first application. Patent extensions (discussed later) and regulatory exclusivities lengthened the period of protection until March 24, 2010.

96. The ’893 Patent contemplated the future ability to have only the R-trans or S-trans enantiomers of compounds of structural formula I. The ’893 Patent also recognized that these compounds could be in acid or salt form.

97. Although the ’893 Patent covered multiple formulations of structural formula I, Warner-Lambert focused on developing and commercializing atorvastatin, the R-trans enantiomer of a particular compound with structural formula I, in calcium salt form.

98. The ’893 Patent thus covered atorvastatin calcium, the product that Warner-Lambert would sell as Lipitor.

Warner-Lambert Fraudulently Obtains the ‘995 Enantiomer Patent

99. Although the ’893 Patent would (and did) provide Warner-Lambert with many years of patent protection—and many years of exclusive sales of Lipitor—Warner-Lambert nevertheless sought to extend this monopoly by any means necessary, including fraud.

100. Warner-Lambert knew that the R-trans enantiomer was the active enantiomer responsible for atorvastatin’s ability to inhibit cholesterol. Warner-Lambert also knew that the PTO would likely reject an application to patent the enantiomer of the racemic mixture of atorvastatin because the enantiomers were already covered by the ’893 Patent; an enantiomer “invention” would either be anticipated by the ’893 Patent or obvious in light of the ’893 Patent. Thus, Warner-Lambert knew that the only way it could bypass the PTO’s restrictions and procure a follow-on enantiomer patent was to fraudulently convince the PTO that the isolated R-trans enantiomer had some “surprising” or “unexpected” characteristic.

101. Senior management at Warner-Lambert instructed the Warner-Lambert researchers to review the pre-existing biologic data for the R-trans enantiomer to come up with some data that the company could use to claim that the activity of the isolated R-trans enantiomer was "surprising" and therefore patentable.

102. Warner-Lambert senior management asked Roth whether the pure R-trans enantiomer had patent coverage. When Roth responded that the R-trans enantiomer was covered under the '893 Patent, senior management asked whether there was anything about the pure R-trans enantiomer that could make it patentable in and of itself. Roth indicated that, despite his years of work with the R-trans enantiomer, he was unaware of any such surprising characteristics.

103. Don Maxwell, Warner-Lambert's vice president of discovery research, subsequently assigned Roth the task of reviewing existing laboratory books to see whether he could find any data that could be portrayed as showing something surprising about the R-trans enantiomer. Roth was instructed to provide any surprising data to Wyeth patent attorney Joan Thierstein.

104. Regarding the instructions from these senior Warner-Lambert officials, Roth has stated,

> [I]f I found something surprising I would provide that. And what I did do was I provided that information to the patent attorney for Warner-Lambert and asked if that was sufficient, and it was and so that was the data that was used.

105. Of course, when senior Warner-Lambert management sent Roth back to the old laboratory notebooks to "find" something that could be mischaracterized as surprising, there was a wealth of knowledge in the scientific community about statins and the formulation of isolated R-trans enantiomers. This state-of-the-art understanding of statin formulations gives context to Warner-Lambert's fraud.

The State of the Art: Knowledge of One Skilled in the Art of Statins in 1989

106. Statins are in the field of synthetic organic chemistry as it applies to the discovery of compounds suitable for use as drugs directed to the regulation of the cholesterol biosynthetic pathway and HMG-CoA reductase inhibitors. One of ordinary skill in the art of statins would possess at least a bachelor's degree in organic or medicinal chemistry; a general working knowledge of statins; several years of bench work in organic molecule synthesis; some general knowledge of biochemistry and enzymology; knowledge of stereochemistry of pharmaceutically active compounds; and knowledge of resolving racemates.

107. In 1989, when Warner-Lambert applied for a patent for the isolated R-trans enantiomer, one skilled in the art would have been knowledgeable about the biological pathway for the synthesis of cholesterol, including that HMG-CoA reductase is the rate-limiting enzyme in the biological pathway for cholesterol produced in an organism. One skilled in the art would also have known that statins were potent inhibitors of HMG-CoA reductase, and that the scientific literature had described *in vitro* assays as methods for testing a compound's ability to inhibit cholesterol synthesis.

108. One skilled in the art would have been aware that mevastatin (compactin) is a natural HMG-CoA reductase inhibitor that exists as a single enantiomer. One would also have been aware that lovastatin (mevinolin), another potent inhibitor of HMG-CoA reductase, had been isolated and was structurally very similar to compactin. One would also have known that both mevastatin and lovastatin have lactones in the R-trans configuration.

109. One skilled in the art would also have been aware that pravastatin (1979), symvastatin (1981), and fluvastatin (mid-1980s) were developed/isolated prior to 1989.

110. One skilled in the art would have understood that pharmaceutical research into improved inhibitors of HMG-CoA reductase was focused on analogues of known statins. One would have been aware that researchers were focused on retaining the lactone ring in known statins while investigating substitutions on the remainder of the molecule.

111. One skilled in the art would have known that the ring-opened form of the upper lactone portion of the previously discovered statins is significantly more active in inhibiting HMG-CoA reductase than the lactone (closed-ring) form.

112. One skilled in the art would have known that HMG-CoA reductase inhibitors are enantiomeric, and that one enantiomer is likely to be more active than the other. One would have known that the biological activity of a racemate in a biological system can be quite different from that of a single enantiomer, and that one enantiomer is approximately twice as active as the racemate in terms of its operation in a target biological system (i.e., one enantiomer is the "active" isomer, while the other is "inactive," and thus the active enantiomer is about twice as active as the racemic mixture). One would also have known that it is desirable to separate and remove the less active enantiomer.

113. In 1989, one skilled in the art would have known that, in the case of HMG-CoA reductase inhibitors, the R enantiomer was very likely to be the active enantiomer and, conversely, that the S enantiomer was very likely to be inactive. One would have known that these expected activities could be known with certainty by isolating and testing the activity of the enantiomers.

114. One skilled in the art would have understood that racemic mixtures can be separated or resolved into the individual enantiomers by well-known methods of separation or resolution.

Similarly, one would have been aware that single enantiomers can be isolated by chiral or achiral synthesis.

115. One skilled in the art would have known that it was common practice among medicinal chemists and others working in the drug discovery field in 1989 to use a single structural formula to represent both enantiomers individually, as well as mixtures of enantiomers. One would have been similarly aware that whether a diagram depicting the structural form for a molecule or class of molecules shows a particular stereochemistry configuration (whether absolute or relative) depends on the context in which the diagram appears. One would have known that if a diagram of a single enantiomer was intended to depict a racemate, to the exclusion of the enantiomer, it was possible to add an additional descriptor, such as (+/-), RS, or (‘rac’), which would make it clear that the structure represented only a racemate.

116. One skilled in the art, given the Original Lipitor Patent, would have known that compounds in the structural formula I were racemic, that there were a discrete number of enantiomers possible from the structural formula, and that there were known methods for dissolving the racemic mixture into the enantiomers.

Warner-Lambert Fraudulently Claims That the R-Trans Enantiomer is Ten Times More Active than the Racemate

117. On July 21, 1989—two years to the day after the ’893 Patent issued—Warner-Lambert and Roth applied for a patent for the R-trans enantiomer, i.e., for the R-trans form of the ring-opened acid described in the ’893 Patent: [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid and “its

lactone form and salts thereof."[9] U.S. Patent Application No. 384187. This application would eventually lead (albeit by fraud) to the issuance of the '995 Enantiomer Patent.

118. Warner-Lambert, including Thierstein, Anderson, and Roth, prosecuted the application from 1989 to 1993. This protracted prosecution shows the materiality of Warner-Lambert's misrepresentations.

119. In the application, Roth and Thierstein claimed, "[i]t is now *unexpectedly found* that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent] . . . *provides surprising inhibition* of the biosynthesis of cholesterol." (Emphasis added). Roth and Thierstein further claimed that "an ordinarily skilled artisan may not predict the *unexpected and surprising inhibition* of cholesterol biosynthesis in the present invention in view of [prior] disclosures." (Emphasis added). In support of this contention, Warner-Lambert presented only one piece of evidence: a short table stating that Warner-Lambert's Cholesterol Synthesis Inhibition ("CSI") assay data demonstrates that the R-trans enantiomer is *one-hundred times more active* than the S-trans enantiomer, and *ten-times more active* than the racemate, in inhibiting the synthesis of cholesterol *in vitro*.

120. Warner-Lambert claimed the "present invention"—the R-trans enantiomer—based on the data presented in the CSI table.

121. A CSI assay measures the ability of a compound to inhibit cholesterol biosynthesis along the entire cholesterol biosynthesis pathway and is one of the most commonly used methods

[9] As part of the application, Roth provided a declaration acknowledging his duty to disclose information material to the examination of the application to the PTO, pursuant to 37 C.F.R. §§ 1.56-1.63. Roth appointed Warner-Lambert's patent attorneys as his attorneys/agents and authorized them to prosecute the application. He further directed that all correspondence related to the patent application be sent to Warner-Lambert attorney Joan Thierstein. The application itself was signed and submitted by Elizabeth M. Anderson, a Warner-Lambert employee.

to test a compound's ability to inhibit the synthesis of cholesterol *in vitro*.[10] The results of a CSI assay are reported as an IC_{50} value, the concentration of a test compound that produces 50% inhibition in the conversion of cholesterol-[14C] acetate to radioactive cholesterol. The CSI assay does not identify the specific step in the cholesterol biosynthetic pathway that is being inhibited, nor is it specific to HMG-CoA reductase.

122. One skilled in the art of statins in 1989—and indeed one skilled in the art even today—would have expected the active R-trans enantiomer to be about twice as active as the racemate in inhibiting cholesterol synthesis. After all, the racemic mixture is simply the active enantiomer combined evenly with the inactive enantiomer (and thus equal amounts of each enantiomer yield an active enantiomer that is twice as active as the mixture).

123. It would indeed be "unexpected" and "surprising" if the activity of one enantiomer were truly ten times that of the racemic mixture. In fact, it would be an extraordinary development in the science of stereochemistry. In reality, Warner-Lambert's claim was a deliberate misrepresentation intended to overcome the statutory limitations governing follow-on patents.

The CSI Table Is Misleading and Affirmatively False

124. Warner-Lambert's biologic data—the CSI Table—was both affirmatively false and presented in an intentionally misleading manner. The CSI Table purports to present reliable scientific data. It does not. Rather, it contains limited data that was cherry-picked from multiple flawed tests conducted over several years using different formulations of various atorvastatin

[10] Two other commonly used methods of measuring a compound's inhibition of cholesterol are the *in vivo* Acute Inhibition of Cholesterol Synthesis ("AICS") assay and the *in vitro* CoA Reductase Inhibition ("COR") assay. The COR assay measures a compound's ability to inhibit HMG-CoA reductase specifically and is typically used to confirm that the activity seen in the CSI assay is attributable to inhibition of the desired target: HMG-CoA reductase.

salts. The reliable data actually shows that the R-trans enantiomer is, as expected, only about two times more active than the racemic mixture—far from the "surprising" tenfold increase that Warner-Lambert claimed.

125. Warner Lambert's CSI Table is misleading because it purports to present reliable and confirmed data but does not do so. The CSI Table does not disclose the source of its data and fails to indicate the number of CSI assays performed, the degree of variation in the test results, what molecules were tested, the time period over which the assays were run, or whether the results presented were drawn from multiple tests. A skilled addressee would likely conclude, therefore, the data had been confirmed by a number of repeat assays and that the CSI Table fairly depicted all relevant data.

126. Warner-Lambert claimed in subsequent litigation that the CSI Table was created by averaging the results of all available CSI screens. This, too, is not true. In fact, Warner-Lambert ran a number of CSI assays—over a multi-year period and on various salt formations—as it tested the R-trans enantiomer of structural formula I before applying for the '893 Patent. The results fluctuated wildly. Rather than averaging these assays—or offering any other valid statistical presentation of the data—Warner-Lambert cherry-picked from among the results in order to generate a table that supported its claim of "surprising activity."

127. In addition, the CSI Table combines results from a number of different CSI assays and compares them to a separate CSI assay. This was contrary to accepted scientific practice in the 1980s, which called for repeated head-to-head tests when providing data of the kind found in the CSI Table. Roth himself has repeatedly acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity. However, the data presented to the PTO for the R-trans enantiomer and S-trans enantiomer were taken from a single run of the same

experiment: CSI 120. And, in bizarre contrast, the data collected for the racemate represents an "average" of five separate assays: CSI 92, CSI 93, CSI 95, CSI 102, and one of three recorded values from CSI 118.

128. Moreover, the five "averaged" assays for the racemate were conducted over a three-year period from July 1985 through October 1988. Calculating an average across different days and experiments was not, and is not, consistent with accepted scientific practices. The results of these five experiments reported for the racemate are so variable that they cannot be averaged together with any reliability or scientifically meaningful result.

129. It is also inconsistent with accepted pharmaco-chemistry to "average" the results of CSI values derived from both opened lactones and separately synthesized sodium salts, as was done here. Four of the assays reflected in the racemate data in the CSI Table (CSI 92, 93, 105, 102) started with the lactone (unopened) form of racemic atorvastatin and were treated with sodium hydroxide to open the lactone ring and to create a sodium salt during the testing process. The fifth assay (CSI 118) started with chemically synthesized sodium salt of racemic atorvastatin prepared by a medicinal chemist.

130. One skilled in the art in 1989 would have been aware that if lactone rings do not fully open when exposed to sodium hydroxide, the presence of inactive material will result in a higher IC 50 value, indicating that the compound is less active than it actually is. One skilled in the art would also have expected that the IC 50 values for the racemic lactones in each of the four CSI assays would be similar, not report a four-fold difference (from .02 (CSI 93) to .09 (CSI 102)). One skilled in the art would also have expected that the IC 50 values for the racemic lactones would be similar to the value of the racemic sodium salt, not report a tenfold difference (from .009 (CSI 118) to .09 (CSI 120)). Such disparate values show that not all of the lactone

rings opened during the test and/or other solubility issues that compromise the accuracy of the data. The large differences were caused by solubility differences, not by the "inherent" differences in ability to retard synthesis.

131. Notwithstanding that accepted scientific standards reject the use of the average value, the CSI Table does not even constitute a true average. As shown in Figure 9 below and although available, Warner-Lambert did not include all results from all conducted CSI assays, omitting the results from at least nine other CSI tests, including CSI 107, CSI 111, CSI 112, CSI 119, CSI 122, CSI 123, CSI 124, CSI 136, and CSI 138.

132. Depending on which assays were included or excluded, the CSI Table could have, and would have, reported very different results. For example, Roth acknowledged that had the results of CSI 107 been included in his "average," there would have been no "surprising" or "unexpected" result. Rather, had CSI 107 been included, the CSI Table would show only the non-surprising, expected twofold increase in the activity of the R-trans enantiomer as compared to the racemate. Roth has claimed that he did not include CSI 107 because he believed that the compounds it tested were not enantiomerically pure; yet, he included the results of CSI 120, which suffered from a similar level of contamination.

133. Similarly, the CSI Table would have shown only this expected twofold increase had Warner-Lambert excluded the results of CSI 118 from its "average." As discussed below, CSI 118 suffered from myriad problems.

134. The fact remains that the R-trans enantiomer is only twice as active as the racemate, regardless of how Warner Lambert, Thierstein and/or Roth manipulated their data.

135. Warner-Lambert's claim that the R-trans enantiomer has surprising activity is false. Warner-Lambert's claim that the R-trans enantiomer is ten times more active than the racemate

is false. Warner-Lambert, including Roth, knew that the R-trans enantiomer is, as would be expected by one skilled in the art, only about twice as active as the racemic mixture.

136. Warner-Lambert, including Thierstein and Roth, deliberately failed to tell the PTO that it possessed data that expressly contradicted representations in its patent specifications.

137. In addition to CSI assays, Warner-Lambert assessed the activity of the R-trans enantiomer, S-trans enantiomer, and the racemate through the *in vivo* AICS assay. The AICS assay—the only screen to be conducted twice and with consistent results—showed a twofold increase in activity of the R-trans enantiomer over the racemate. But Warner-Lambert never submitted the AICS data to the PTO.

138. Warner-Lambert also assessed the activity of the R-trans enantiomer, S-trans enantiomer, and the racemate through the *in vivo* COR assay. The COR data was consistent with a twofold increase in activity of the R-trans enantiomer over the racemate. But Warner-Lambert never submitted the COR data to the PTO.

139. Warner-Lambert's own research reports conclude that the R-trans enantiomer was approximately twice as active as the racemate. A May 31, 1989 report signed by Dr. Sliskovic states that the R-trans enantiomer "was approximately *twofold* more active at inhibiting cholesterol synthesis acutely *in vivo* compared to the racemic mixture. . . . *This is to be expected* if 50% of the racemic salt is the inactive isomer." (Emphasis added). A June 1, 1989 report signed by Roth also reported a twofold increase in activity of the active enantiomer over the racemate: "[a]s expected, [the R-trans calcium salt] was twofold more potent than . . . the racemic calcium salt, which contains 50% inactive isomer." Other internal memoranda from September and December 1989 similarly conclude that, as expected, the R-trans enantiomer was twice as active as the racemate. But Warner-Lambert never shared its conclusions with the PTO.

140. Roth and Warner-Lambert knew and intended that a person skilled in the art would read the CSI Table as (1) fairly reflecting all of the appropriate CSI data available to Warner-Lambert for the relevant compounds, and (2) representing that the data as a whole provided reasonable grounds for the findings set forth in the CSI Table. Instead, Roth, Theirstein, and Warner-Lambert presented data that was affirmatively false, and intentionally presented data in a misleading manner, so that the CSI Table would be read as demonstrating a tenfold increase in activity and, therefore, support patentability.

141. Roth, Thierstein, and Warner-Lambert knew that the CSI data did not provide any "surprising" results. After all, Warner-Lambert scientists, including Roth, had conducted the various CSI assays over a period of more than three years. Certainly, if the assays had disclosed anything surprising—certainly something as shocking as a ten-fold increase in biological activity—the scientists would have learned of the surprising results, in real time, as the tests unfolded. But none of Warner-Lamberts' internal documents (produced to date in related litigation[11]) or any of the literature published by Dr. Roth and his team concerning the discovery of atorvastatin refer to, or even suggest, a ten-fold increase in activity.

142. Instead, it was only after senior Warner-Lambert managers (not the scientists) instructed Roth to go back and "find" something surprising in the data, and after Warner-Lambert cobbled together an invalid hodge-podge analysis of different tests on different compounds, that the claimed ten-fold increase in biological activity materialized.

143. Furthermore, accepted chemistry practice in 1989 counseled to conduct controlled tests of the proposed hypothesis, *i.e.*, that there were some "surprising" attributes of the isolated R-trans enantiomer over the racemic mixture. Accordingly, if Warner-Lambert genuinely wanted

[11] *See Ranbaxy Australia Pty Ltd. v. Warner-Lambert Co. LLC*, 2006 FCA 1787 (Dec. 20, 2006).

to determine whether the R-trans enantiomer had any "surprising" attributes, it should have conducted new tests to research its hypothesis. Instead, Roth simply reviewed old data in order to create an impression, albeit a false one, of some type of "surprising" attribute.

The Initial Rejection: The PTO Determines the Claimed Compounds Are Anticipated By the '893 Patent

144. On March 22, 1990, pursuant to 35 U.S.C. 102(b), the PTO rejected all claims in the initial application as anticipated by (that is, covered by) the '893 Patent. The PTO determined that the '893 Patent "restrict[ed] the invention to the trans-isomers and . . . specif[ied] the R*, R* configuration. Thus, the claimed compounds, salts, compositions, and method are considered to be anticipated by [the '893 Patent]." Put simply, the PTO rejected Warner-Lambert's patent application for the isolated enantiomer because the invention was already covered by the claims in the Original Lipitor Patent.

145. The principles of "anticipation" and "non-obviousness" are distinct, but related, concepts under patent law. A proposed invention may be rejected under 35 U.S.C. § 102(b) as being anticipated by a previous patent. Alternatively, even if a proposed invention is not identically disclosed or described as set for in § 102, a patent may be rejected due to obviousness under 35 U.S.C. § 103 "if the differences between the subject matters sought to be patented and the prior art such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Because the patent examiner (the "Examiner") had concluded that the Original Lipitor Patent anticipated (that is, already covered) the isolated R-trans enantiomer form of atorvastatin, the Examiner did not need to reach the concept of obviousness.

146. In response to this rejection, Warner-Lambert argued against anticipation on technical grounds that the '995 Patent application addressed specific enantiomers, while the '893 Patent

addressed only racemates, noting that "the presently claimed compounds are for individual enantiomers and therefore differ from the teaching in [the '893 Patent] only to mixtures of enantiomers."

147. Warner-Lambert, through Thierstein, argued that the '893 Patent did not specifically identify, and therefore did not technically "anticipate," the R-trans enantiomer:

> In molecules of the kind disclosed in [the '893 Patent], each possible isomer also exists in two forms which depend on a configuration which is expressed in absolute terms relative to the remainder of the molecule. The forms are denoted as an R form and an S form. These two forms are recognized by an ordinarily skilled artisan to be enantiomeric forms each having a specific chirality. In [the '893 Patent] the disclosure is not limited to compounds having such a specific chirality. Thus, each isomer of [the '893 Patent] is a mixture of enantiomers and not the currently claimed individual enantiomers having an R chirality.

Roth himself rejected this argument in later patent litigation.

148. The PTO issued a final rejection on anticipation grounds on November 7, 1990. The Examiner determined that the '893 Patent described the R-trans enantiomer:

> Applicant's arguments . . . have been carefully considered, but such are not persuasive. Where a reference discloses a genus or compound of similar structure which are sufficiently limited in number, the reference is deemed to provide description of those compounds just as specifically as if they were identified by name.

The Examiner observed that to isolate the claimed invention, the R-trans enantiomer, from the compounds disclosed in the '893 Patent, "one merely has to select from the limited possibility of isomers . . . and separate them using conventional techniques." Thus, the '893 Original Lipitor Patent anticipated the R-trans enantiomer.

149. Warner-Lambert abandoned the application following the final rejection on anticipation grounds.

The Renewed Application: Warner-Lambert Submits the Roth Declaration, Again Falsely Claiming that the R-Trans Enantiomer is Ten Times More Active than the Racemate

150. Having been rejected by the PTO once, Warner-Lambert requested a retroactive extension of time to revive its application on February 29, 1991. Included in that request was a preliminary amendment of its application and a supporting declaration from Dr. Bruce Roth ("Roth Declaration"). In it, Dr. Roth falsely professed to present evidence of an unexpected tenfold increase in activity.[12]

151. The Roth Declaration was submitted in order to overcome an obviousness rejection and to support the patentability of the R-trans enantiomer. Accordingly, it again claims a "surprising" and "unexpected" tenfold increase in activity. It (falsely) professes to present seemingly objective evidence of an unexpected characteristic of the isolated R-trans enantiomer. Warner-Lambert, through Thierstein and Roth, claimed this characteristic would allow issuance of an R-trans enantiomer patent despite the fact that the claimed invention was *prima facie* obvious in light of the Original Lipitor Patent. The Roth Declaration simply presented more of the same: misleading and affirmatively false biologic data.

Warner-Lambert Admits that the R-Trans Enantiomer Is *Prima Facie* Obvious

152. While continuing to argue that the proposed R-trans enantiomer patent was not technically anticipated by the Original Lipitor Patent, Warner-Lambert also raised, on its own, the issue of obviousness. Indeed, Warner-Lambert admitted that the R-trans enantiomer was *prima facie* obvious in light of the '893 Patent.

[12] The patent specification accompanying the renewed application also contained a chart (the "CSI Chart") showing that the R-trans enantiomer has ten times greater activity than the corresponding racemate. The information contained in this chart is identical to that presented in the original application.

153. In its remarks in support of the renewed patent application, Warner-Lambert quoted the U.S. Court of Customs and Patent Appeals in *In re May and Eddy*, 197 USPQ 601, 607 (1978): "As recognized in *In re Williams*, 36 CCPA 756, 171 F.2d 319, 80 USPQ 150 (1948), the novelty of an optical isomer is not negated by the prior art disclosure of its racemate."[13] "Clearly," Warner-Lambert asserts, "this case law is applicable here."

154. In *May*, the applicant conceded *prima facie* obviousness, but submitted "rebuttal evidence" in the form of four declarations indicating that it was "unexpected" that the compounds in question did not exhibit the addictive qualities of most opiates. The PTO refused to consider the rebuttal evidence. The U.S. Court of Customs and Patent Appeals reversed. "[B]alancing the *prima facie* case of obviousness made out by the PTO against appellants' objective evidence of nonobviousness," the court concluded, "the subject matter of claims 11-13 would not have been obvious to one of ordinary skill in the art." Thus, *May* stands for the proposition that, when a claimed invention is *prima facie* obvious, an applicant may provide declarations identifying objective evidence of a surprising characteristic to overcome an obviousness rejection.

155. Warner-Lambert purported to do just that in its renewed application, thereby conceding that the R-trans enantiomer was *prima facie* obvious. In the remarks, Warner-Lambert states:

> Following the Williams case Applicant also now provides by a declaration a comparison among each enantiomer and mixture of enantiomers. This comparison is provided to overcome the Roth reference [that is, the reference in the '893

[13] In *Williams*, as here, the applicant sought a patent on a particular enantiomer. The *Williams* court determined that there was no evidence in the record demonstrating actual knowledge that the original patented product was racemic, and thus the idea of resolving the product into components would not have occurred to one skilled in the art. In contrast, the racemic nature of the compound at issue in this litigation was well-known at the time the Original Lipitor Patent was issued.

> Patent] of the present rejection to facilitate a finding of patentability and moving the prosecution toward resolution of pertinent issues. In other words, *although Examiner has not included a rejection under 35 U.S.C. 103 [for obviousness] Applicants are including a rebuttal of such rejection to comply with the Williams case law.*

(Emphasis added). Warner-Lambert further describes the Roth Declaration as "provid[ing] the data as set out in the present application in a manner to provide patentability to the application,"[14] and states, "in other words, *the declaration is submitted to provide evidence of patentability* to the instant invention." (Emphasis added).

The Roth Declaration is Misleading and Affirmatively False

156. Warner-Lambert submitted the Roth Declaration in an effort to overcome an otherwise inevitable rejection on obviousness grounds. The Roth Declaration states that "the antihypercholesterolemia properties of ["R-enantiomer," or "Compound I"] and ["Senantiomer," or "Compound II"] and mixtures thereof are assessed using essentially the CSI screen that is disclosed in [the '893 Patent]." The Roth Declaration further states that the R-trans enantiomer has "activity grater than *fifty-fold more* than that of Compound II and which indicates activity *at least ten-fold more* than that of the racemate." It also contained a new Roth Declaration Table.

157. The Roth Declaration intentionally gives the false impression that the CSI assay data represents all reasonably available and proper information. Specifically, the Roth Declaration states that the available "datum from the compound I" (the R-trans enantiomer) and "the datum from the racemate" (the S-trans enantiomer) are presented below, implying (at minimum) that the values given reflect all appropriate, reasonably available CSI assay data. The Roth Declaration further claims that "the difference in the data . . . among Compounds I, II and racemate shows the activity of Compound I is *surprising and unexpected* because if the

[14] Warner-Lambert thus at least tacitly acknowledged that the CSI Table previously submitted in the patent specification was not sufficient to establish patentability.

Compound II is accepted as inactive, the activity of the Compound I would be expected to be only twice that of the racemate mixture."[15] (Emphasis added).

158. The Roth Declaration, like the CSI Table, purports to present reliable scientific data but does not disclose the source of that data. A skilled addressee would conclude that Warner-Lambert would not have included the CSI Table in the specification in such an unqualified way unless the data had been confirmed by a number of repeat assays.

159. In fact, the Roth Declaration presents unreliable data from a single, deeply flawed screen—CSI 118—and is affirmatively false and misleading.

160. In addition to generating a value for the racemic sodium salt, which Roth used in the CSI Table in the patent specification, CSI 118 compared all three forms of calcium salt (R-trans, S-trans, and racemate) in a single head-to-head assay. The screen was never re-rerun to confirm the reported results.[16] The test results are unusable for a number of reasons.

161. First, in order to obtain accurate IC_{50} values, the concentration of the test solutions must be known prior to testing. Warner-Lambert did not determine the concentration of its test solutions prior to conducting the CSI 118 test. Without accurate information about the concentration of the solutions used in the CSI 118 test, the IC_{50} values obtained in CSI 118 are unreliable and cannot be used to demonstrate a tenfold increase in activity of the R-trans enantiomer over the racemate.

[15] Roth's declaration concludes with a paragraph stating, in part, that "these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both . . . and that such willful false statements may jeopardize the validity of the above identified US patent application . . . or any patent issuing thereon."

[16] Roth admitted that he did not conduct any additional test to confirm that the biologic data presented in the patent was in fact correct: "it is true that [the biologic data that was included in the patent] went out without any subsequent tests being asked for by me to repeat that data."

162. Second, Warner-Lambert's own lab books show that the compounds in CSI 118 did not dissolve completely in the stock solution. Using non-homogeneous suspensions can result in variations in the concentrations of the compound in the assay solution leading to wide variation in the results obtained. Given this limitation, the most that the CSI 118 results can be said to determine is whether a compound has *any* activity, not whether a compound has a twofold, threefold, or tenfold increase in activity over another compound.

163. Third, as Roth has acknowledged, an acceptable CSI test should record similar results for the racemic sodium salt and the racemic calcium salt. Yet, in CSI 118, the results of the racemic calcium salt (.257) were almost twenty-five times the results of the racemic sodium salt (.00977). The difference was so great that the IC_{50} value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt; that is, the R-trans enantiomer, *the active enantiomer*, of the calcium salt was *less active* than the racemate of the sodium salt. This should have alerted the scientists that something was wrong with the screen, likely a problem related to solubility issues.

164. Finally, the claim in the Roth Declaration of ten times greater activity is affirmatively false, as the activity of the isolated R-trans enantiomer is not in fact ten times greater than the racemate. Had Warner-Lambert employed a scientifically acceptable testing process, the data would have revealed that the R-trans enantiomer had, at best, a twofold advantage over the racemate.

165. Roth and Warner-Lambert were aware of the numerous problems with CSI 118 and knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different results for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results indicating that the racemate of one salt was more potent than the R-

trans enantiomer of another salt, they used this questionable and unreliable data to support the false claim that the isolated R-trans enantiomer has ten times greater inhibition of cholesterol synthesis than the racemate. They specifically claimed that this was "a surprising level of activity" which, in turn, supported patentability. Dr. Roth has admitted under oath that he submitted CSI data for the purpose of demonstrating "a surprising level of activity" which therefore supported patentability:

> Q. So [the biologic data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?
> A. [Dr. Roth:] Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we thought would be novel and surprising and therefore would support patentability.

166. Warner-Lambert knew that a person skilled in the art would read the Roth Declaration as fairly reflecting all appropriate CSI data for the relevant compounds that was available to Warner-Lambert, and as representing that the data as a whole provided reasonable grounds for the findings set forth therein. Roth and Warner-Lambert intended that the Roth Declaration be read as suggesting a tenfold increase in activity and therefore supporting patentability. In supplying the PTO with false claims, including a claim of ten times greater activity, and false and unsound data, and in packaging that data to have a false appearance of reliability, Warner-Lambert committed fraud on the PTO.

The Final Rejection: The PTO Determines that the R-Trans Enantiomer is Anticipated

167. The PTO Examiner issued a final rejection of the follow-on patent application on September 16, 1991, rejecting all claims as anticipated by the '893 Patent for the reasons set forth in the two rejections issued in 1990.

The Appeal: the Patent Board of Appeals Determines that the R-Trans Enantiomer is Prima Facie Obvious

168. On January 15, 1992, Warner-Lambert appealed the Examiner's rejection to the Board of Appeals, asserting that "[t]he R isomer as claimed appears to be at least *100 times more active than its corresponding S isomer and more than 10 times more active than the mixture*. Under ordinary circumstances one would have expected only a two-fold difference between the particular R isomer and the mixture." (Emphasis added). The appeal was signed by Attorney Ronald A. Daignault, a Warner-Lambert employee. Daignault states, "the present invention describes the particular R isomer which is found to have *greater than 10 times the activity* of the compound described in the prior art reference, namely, the racemic mixture," "the compound of the present invention . . . does not produce substantially the same result since it has *greater than 10 times the ac*tivity than the reference compound," and "the R isomer is the most desired and the most *surprisingly active* isomer of the two possibilities if one is to select from the trans compounds." (Emphasis added).

169. Acknowledging that the isolated R-trans enantiomer is *prima facie* obvious over the Original Lipitor Patent, Warner-Lambert argued that the obviousness is overcome by the surprising and unexpected activity claimed in the Roth Declaration: "The examiner's rejection is erroneous as a matter of law by applying the facts of the present case to the wrong law. The issue here is whether an optical isomer is novel over its prior disclosed racemic mixture. The law as state[d] in May and Eddy affirming In re Williams says yes."

170. The Examiner filed an answer to Warner-Lambert's appeal on March 24, 1992. The Examiner alleged no new grounds for denial of the application, instead reiterating the previously disclosed grounds and stating that "even if a preferred isomer were not disclosed [by the '893

Patent], one skilled in the art expects one of the individual isomers to be more active than the other since this, too, is knowledge contemporary in the art."

171. On October 19, 1992, the Board of Appeals overturned the Examiner's rejection of the application on the basis of anticipation, concluding that the '893 Patent did not technically anticipate the R-trans enantiomer:

> at best, [the '893 Patent] only describes the trans racemate containing the R-trans and the S-trans isomers in admixture. Nowhere does [the '893 Patent] state or suggest which optical isomer is preferred and, moreover, does not specifically mention how one skilled in the art could make the pure optical isomer separately. In view of the above, we are unable to subscribe to the examiner's contention that the ['893 Patent] anticipates the claimed subject matter.

172. However, the Board recommended to the Examiner that, upon remand, the patent should be rejected on the basis of *obviousness*:

> Upon further prosecution of this application before the examiner, we recommend that the examiner analyze the claimed subject matter under the provisions of § 103 of 35 USC. *An obviousness rejection of claims directed to an optically pure isomer appears to be in order when, as here, (1) the product of the prior art is known to be racemic and (2) where methods for resolving the racemic mixture into the pure optically active isomers are known to those skill[ed] in the art.*

The '995 Patent Issues: PTO Relies on Biologic Data to Overcome Obviousness

173. On March 16, 1993, apparently without any further formal proceedings or briefing, the PTO issued a Notice of Allowability for the follow-on, isolated R-trans enantiomer patent application. U.S. Patent Number 5,273,995 (the '995 Enantiomer Patent) was issued on December 28, 1993.[17]

174. Warner-Lambert had presented the results of CSI screens in both the '995 Patent specification and the Roth Declaration to support its contention that the R-trans enantiomer was surprisingly and unexpectedly ten times more active than the racemate and therefore not obvious

[17] Defendant Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '995 Patent.

in light of the '893 Patent. Warner-Lambert made this representation in the original application for the follow-on patent, in the Roth Declaration, in its appeal to the PTO, and in the final patent specification. This representation as knowingly false when made. This is the only "surprising" activity of the isolated R-trans enantiomer that was discussed in the '995 Patent application, and it was, therefore, the sole reason that Warner-Lambert was able to overcome an obviousness rejection.

175. The PTO relied on the Roth Declaration and the CSI Table to find that the R-trans enantiomer was not obvious in light of the '893 Patent. The Board of Appeals had explicitly (i) directed the Examiner to re-evaluate the application for obviousness, and (ii) stated that an obviousness rejection appeared to be appropriate. The only "surprising" or "unexpected" characteristic of the isolated R-trans enantiomer that Warner-Lambert had claimed was the tenfold increase in activity compared to the racemic mixture. The only evidence presented in support of those claims was contained in the patent specification (the CSI Table) and the Roth Declaration, both of which, as described above, were misleading and false. Thus, upon reevaluating the application in accordance with the Board of Appeals' directive, the Examiner relied on Warner-Lambert's claim of "surprising" and "unexpected" activity and determined that the evidence presented in support of that claim (in both the patent specification itself and the Roth Declaration) were sufficient to overcome a rejection on obviousness grounds.

176. The inclusion of particular language and data in the patent specification itself confirms that the PTO relied on both the claim of "surprising" and "unexpected" activity and the data that Warner-Lambert submitted in support of that claim. The specification states, "[i]t is now unexpectedly found that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent], . . . that is [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-

methylethyl)-3-phenyl-4-[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, provides surprising inhibition of the biosynthesis of cholesterol." The specification further states that "an ordinarily skilled artisan may not predict the unexpected and surprising inhibition of cholesterol biosynthesis of the present invention in view of [prior] disclosures."

177. Accordingly, the '995 Enantiomer Patent would not have issued but for Warner-Lambert's fraud.

E. Warner-Lambert Intended to Deceive the PTO

178. Warner-Lambert's false claims and data were made with knowledge they were false and misleading and with the specific intent that the PTO rely on those claims in order to issue a follow-on patent. Roth and Warner-Lambert knew that a person skilled in the art would interpret the CSI Table and the Roth Declaration as representations that the results therein fairly reflected all scientifically reliable CSI data for the relevant compounds that was available to Warner-Lambert, and that the data as a whole provided reasonable grounds for the findings set forth therein. Roth and Warner-Lambert intended that the CSI Table and the Roth Declaration be read as suggesting a ten-fold increase in activity, an assertion they knew to be false, so that the documents would support the application for the follow-on patent.

Warner-Lambert Manipulated the Existing Biologic Data to Show a Ten-Fold Increase in Activity and Intentionally Presented False Information

179. Warner-Lambert manipulated the existing biologic data in order to show a tenfold increase in activity. It did so with the specific intent to deceive the PTO.

180. Warner-Lambert has acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity, yet it did not present such head-to-head data in support of its claim that the R-isomer has ten times the activity of the racemate. Instead, Warner-Lambert selected results from various tests conducted on different days, using different salts, and

suffering from various flaws, and it presented these manipulated results in the CSI Table that was included in the patent specification. Warner-Lambert's gross departure from accepted chemistry practice—by a company fully aware of what accepted chemistry practice would have required—demonstrates Warner-Lambert's knowledge that its statements were false and its specific intent to deceive.

181. Warner-Lambert acknowledged that if it had included the results of CSI 107 in its "average," the data would not have suggested any surprising or unexpected result. Warner-Lambert has claimed that it did not include CSI 107 in its calculations because it believed that the compounds it tested were not enantiomerically pure, yet it included the results of CSI 120, which suffered from a similar level of contamination. Warner-Lambert's gross departure from accepted chemistry practice demonstrates Warner-Lambert's knowledge that its statements were false and its specific intent to deceive.

182. Warner-Lambert claimed that it did not provide the PTO with data from CSI 119 because CSI 119 was not a head-to-head comparison, and it claimed to believe that it was inappropriate to compare individual data points from different experiments. Yet, Warner-Lambert used different data points from multiple experiments to generate the data contained in the CSI Table. Warner-Lambert's gross departure from accepted chemistry practice demonstrates Warner-Lambert's knowledge that its statements were false and its specific intent to deceive.

183. Warner-Lambert included one of the three results from CSI 118 in the CSI Table in order to show an alleged ten-fold increase in activity. The sodium salt prepared by opening the racemic lactone in CSI 92, 93, 95, and 102 should have given substantially identical, or at least very similar, values to the racemic sodium salt that was separately prepared by a medicinal chemist in CSI 118. Yet, the results for the racemic sodium salt in CSI 118 differ from the results

of the four lactone CSI tests by a factor of ten. Warner-Lambert's gross departure from accepted chemistry practice demonstrates Warner-Lambert's knowledge that its statements were false and its specific intent to deceive.

184. In CSI 118, the results of the racemic sodium salt and racemic calcium salt are vastly different, showing as much as a twenty-five-fold difference. The difference was so great that the IC_{50} value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt—that is, the R-trans enantiomer of the calcium salt was less active than the racemate of the sodium salt. This difference should have been a red flag that something was wrong with the screen, likely a problem related to the solubility of the compounds. Instead, Warner-Lambert used this questionable data to support the false claim that the R-trans enantiomer has a ten-fold greater inhibition of cholesterol synthesis as compared to the racemate.

185. Warner-Lambert was aware of the numerous problems with CSI 118 identified above, and it knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different results for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results that showed the racemate of one salt was more potent than the R-isomer of another salt, Warner-Lambert used this inconsistent outcome to further substantiate its claim that the R-isomer was ten times more active than the racemate in inhibiting cholesterol synthesis.

186. Warner-Lambert's patent attorneys submitted to the PTO the misleading and false Roth Declaration, the false and misleading Roth Declaration Table, and the misleading and false CSI Table, generated by Roth and others, in furtherance of a deliberately planned and carefully executed scheme to defraud the PTO in order to gain approval of the '995 Patent application.

Warner-Lambert Admits that the Patent Specification Claims a Surprising Ten-Fold Increase in Activity

187. At numerous points in the prosecution of the '995 Patent, Warner-Lambert and Roth stated that the "surprising" characteristic of the isolated R-trans enantiomer was that it had ten-times greater than the activity of the racemic mixture. Warner-Lambert knew that both the CSI Table and Roth Declaration presented false information about the activity of the R-trans enantiomer as compared to the S-trans enantiomer and the racemate. To acknowledge in court that the only claimed "surprising" characteristic of the R-trans enantiomer was false would result in the loss of the '995 Patent and/or its foreign counterparts. Thus, in subsequent patent litigation, Roth and Warner-Lambert tried to shy away from admitting that Warner-Lambert had ever claimed that the surprising feature of the R-trans enantiomer was a tenfold increase in activity over the racemate.

188. Roth's evasive testimony on this topic is illustrative:

> Q. I suggest to you that you either do or do not rely on those figures. If you want to put out a merely qualitative statement that you have surprising activity you can put it in words. If you put it out in figures that suggests [sic] that it is a very surprising level of activity, being a 10-fold difference?
>
> A: But I believe the words we used were a surprising level of activity. We didn't say that it was surprising because it was a 10-fold difference. We simply said that it was surprising, the numbers suggest 10-fold. But frankly, again, anything more than twofold would be surprising. We didn't claim 10-fold in the patent. We said it was surprising.
>
> Q: You didn't put a qualification to the numbers that you give in the patent to say "beware of these numbers. We're only really saying that we get a better than two-fold improvement"; no mention of that, was there?
>
> A: What we say is that the compound has surprising activity and then we put data into the patent which supported the surprising level of activity. I don't think that we actually comment on the data except to say that it's surprising. The data is what the data is.

Q: The data on its face quantify that is surprising level of activity, does it not, Dr. Roth?

A: There are numbers given, yes.

Q: So it quantifies that surprising level of activity?

A: What do you mean by that?

Q: Do you know what the meaning of the word "quantifies" is?

A: There are numbers that are given. Again, we don't make any claims; all we say is that it's surprising. The numbers are what the numbers are.

189. Roth was ultimately forced to concede that the biologic data contained in the patent specification purports to show a ten-fold increase in activity, and that Warner-Lambert had included that data in the specification for that reason:

Q: And you wanted those numbers to be taken at face value, did you not?

A: I'm not sure I know what you mean.

Q: What?

A: The data is what the data is. The data was included to support the rising level of activity. What the numbers suggest is that it's something like 10-fold, but we don't state that. We simply – what we simply do is we say it's surprising.

Q: Isn't it a fair reading of this passage on page 8 that having said it's surprising that you are saying now here is why and you set out figures which show a 10-fold increase and you don't provide any qualification at all to those numbers?

A: That is true. We simply report the data.

190. Roth acknowledged "[t]he data is what the data is," "the numbers are what the numbers are," and that "the data was included to support the surprising level of activity. What the numbers suggest is that it's something like 10-fold . . . ." The numbers submitted to the PTO show, based on cherry-picked test results, that the R-trans enantiomer is ten times more active

than the racemate. In reality, the R-trans enantiomer is, as expected, only about twice as active as the racemate.

Warner-Lambert Intended for the PTO to Rely on the False Data and Claims

191. Roth has admitted under oath that he submitted CSI data for the purpose of supporting a surprising level of activity which therefore supported patentability: "the biologic data that was included in the patent I felt demonstrated and supported a surprising level of biological activity."

> Q. So [the biologic data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?
>
> A. Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we thought would be novel and surprising and therefore would support patentability.

F. FDA Approval: The FDA approves Lipitor and the Original Lipitor Patent Provides Years of Patent Protection

192. On June 17, 1996, Warner-Lambert submitted a new drug application under Section 505(b) of the FDCA and Section 314.50 of Title 21 of the Code of Federal Regulations, seeking approval to sell atorvastatin calcium, *i.e.*, the isolated R-trans enantiomer formulated as a calcium salt. On December 17, 1996, the FDA approved atorvastatin calcium—now named "Lipitor"—for the treatment of hypercholesterolemia and mixed dyslipidemia. The FDA initially approved 10 mg, 20, mg, and 40 mg tablets, adding approval of 80 mg tablets on April 7, 2000.

The Orange Book Listings for the '893 and '995 Patents

193. Following approval, Warner-Lambert listed both the '893 Original Lipitor Patent and the fraudulently obtained '995 Enantiomer Patent in the Orange Book. When it did so, Warner-Lambert knew that it had procured the '995 Enantiomer Patent through actual fraud on the PTO.

194. Because Warner-Lambert listed both patents in the Orange Book, a generic company seeking approval for an ANDA for generic atorvastatin calcium was required to file a Paragraph IV certification as to both the '893 and '995 Patents if it wished to enter the market before the expiration of the patents. As Warner-Lambert knew and intended, this certification would trigger Warner-Lambert's ability to file infringement litigation, which in turn would trigger the Hatch-Waxman statutory delays for FDA generic approval (i.e., the 30-month stay of ANDA approval).

195. At the time of FDA approval of Lipitor, the '893 Original Lipitor Patent was scheduled to expire on May 30, 2006. The '995 Enantiomer Patent would not expire until December 28, 2010.

196. The Pfizer Defendants also listed the following patents in the Orange Book as covering Lipitor: 6,126,971 (the "'971 Patent"); 5,686,104 (the "'104 Patent") (together, the "Unasserted Formulation Patents"); and 5,969,156 (the "'156 Patent"). No reasonable litigant would have had any expectation of succeeding against Ranbaxy (or any other of the significant generic manufacturers) on a claim alleging infringement of those patents. Such an infringement claim would have been an objectively baseless sham.

The '893 Original Lipitor Patent Protected the Lipitor Franchise for Years

197. Shortly after FDA approval, Warner-Lambert applied for an extension of the patent term of the '893 Patent under 35 U.S.C. § 156. Section 156 provides that the period of patent protection may be extended to account for the time lag between the issuance of a patent covering the active ingredient in a new drug and FDA approval of that drug.

198. Warner-Lambert asked the PTO to extend Lipitor's period of market exclusivity granted by the '893 Original Lipitor Patent—not the '995 Patent—for about three years and four

months. That is, Warner-Lambert took the position that the '893 Patent covered the isolated R-trans enantiomer, atorvastatin, in calcium salt form.

199. Warner-Lambert informed the PTO that (i) the FDA approved Lipitor, (ii) the active ingredient in the drug Lipitor is atorvastatin calcium, and (iii) atorvastatin calcium is covered by the '893 Patent. Warner-Lambert claimed that the '893 Original Lipitor Patent claims atorvastatin calcium as a new chemical entity (Claims 1-4), as a pharmaceutical composition (Claim 8), and as a method for using it to inhibit cholesterol biosynthesis (Claim 9).

200. Claim 1 requires "a compound of structural formula I" or "a hydroxyl acid or pharmaceutically acceptable salt thereof, corresponding to the opened lactone ring of the compounds of structural formula I above." In the extension application, Warner-Lambert claimed that Lipitor is a pharmaceutically acceptable salt of structural formula I, ad is thus covered by Claim 1 of the Original Lipitor Patent.

201. As a result, the PTO extended the term of the '893 Patent until September 24, 2009.

202. Thereafter, Warner-Lambert sought and obtained six additional months of marketing exclusivity from the FDA for pediatric testing. Accordingly, the expiration of the '893 Patent was March 24, 2010.

203. Warner-Lambert also sought and obtained a six-month extension for pediatric testing for the '995 Enantiomer Patent. As a result, the expiration date of the '995 Enantiomer Patent was June 28, 2011.

204. In total, the '893 Patent and the '995 Patent would provide almost fifteen years of patent exclusivity to market and sell branded Lipitor: the Original Lipitor Patent would provide protection from the January 1997 launch until March 2010, and the fraudulently obtained '995

Patent could potentially tack on another 15 months of protection from generic Lipitor competition.

The 1997 Launch of Lipitor

205. Warner-Lambert chose Pfizer to help market Lipitor.

206. After launching in January 1997, Lipitor reached $1 billion in domestic sales within its first twelve months on the market. By the end of 1998, Lipitor was available for sale in fifty countries. In October 1997, 30% of all new U.S. statin prescriptions were written for Lipitor.

G. After launch, Warner-Lambert and Pfizer obtained and listed additional patents.

207. Subsequent to the 1997 launch of Lipitor, Warner-Lambert (and later Pfizer) procured additional patents covering particular (and narrow) processes or formulations ostensibly relating to versions of atorvastatin calcium.

208. First, in November of 1997, Warner-Lambert procured U.S. Patent No. 5,686,104 (the "'104 Patent," expiry January 19, 2013), and in October of 2000 procured U.S. Patent No. 6,126,971 (the "'971 Patent," expiry November 11, 2014). Both the '104 and '971 Patents cover particular, and narrow, ways of formulating atorvastatin calcium with various excipients to stabilize the finished pharmaceutical product. These two patents are referred to as the "Unasserted Stabilization Formulation Patents;" "unasserted" because despite later efforts by generic companies to enter the market, Pfizer never asserted these two patents against any of them; "stabilization" because the composition mentioned in the patents contemplates a particular way of achieving stabilization in the final product; and "formulation" because the two patents only cover two narrow formulations of atorvastatin calcium products.

209. Second, in October of 1999, Warner-Lambert procured U.S. Patent No. 5,969,156 (the "'156 Patent," expiry July 8, 2016). Generally speaking, the '156 Patent is for the crystalline

form of atorvastatin calcium (not amorphous). To obtain this patent, Warner-Lambert told the PTO that around the end of its safety and efficacy studies in 1995, it had reformulated its atorvastatin calcium from an amorphous to a crystalline form.

210. Third, in July 2000, Warner-Lambert procured U.S. Patent No. 6,274,740 (the "'740 Patent," expiry July 16, 2016). In August of 2001, Warner-Lambert acquired U.S. Patent No. 6,087,511 (the "'511 Patent," expiry July 16, 2016). Both the '740 and '511 Patents are process patents, which claim a specific process for making amorphous atorvastatin calcium using crystalline Form I atorvastatin as a starting material. These two patents are called the "Process Patents."

211. Pfizer listed the Unasserted Stabilization Formulation Patents and the '156 Patent in the FDA Orange Book as covering Lipitor. As a practical matter, however, Pfizer knew that would-be generic makers could design-around these narrow patents. The Process Patents were not listed in the Orange Book; because patents for a particular process to make a drug, they are ineligible to be listed there.

H. Pfizer Files Sham Litigation Against Ranbaxy Based on the '893 and '995 Patent

212. Ranbaxy was the first to file an ANDA for generic atorvastatin calcium. Ranbaxy was also the first stymied by Pfizer's allegation that its product infringed the '995 Enantiomer Patent.

213. On August 19, 2002, Ranbaxy filed ANDA 76-477, seeking approval to sell a generic version of Lipitor. As the first to file an ANDA for generic atorvastatin calcium, Ranbaxy was entitled to 180 days of marketing exclusivity. Pursuant to the relevant provisions of the FDCA, no other ANDA applicant for generic Lipitor could receive FDA approval until the expiration of Ranbaxy's period of marketing exclusivity. The exclusivity period would not commence until the earlier of Ranbaxy's actual commercial marketing of the generic drug product or a final court

decision finding that all patents listed for Lipitor in the Orange Book were invalid or not infringed.

214. Beginning in late 2002, Ranbaxy sent four Paragraph IV certification letters to Pfizer with respect to all patents listed in the Orange Book, including the '893 and '995 Patents. In these letters, Ranbaxy asserted that no valid patent claims covering Lipitor would be infringed by the sale, marketing, or use of Ranbaxy's generic product.

215. On February 21, 2003, Pfizer filed an action against Ranbaxy in the United States District Court for the District of Delaware, alleging infringement of the '893 and '995 Patents. Pfizer did not allege infringement of the Unasserted Formulation Patents or the '156 Patent. By operation of Hatch-Waxman, Pfizer's filing suit within forty-five days blocked approval of Ranbaxy's ANDA for thirty months.

216. From 2003 to 2006, the infringement litigation progressed through discovery, a jury-waived trial (in 2004), a district court decision (in 2005), and an eventual appeal and decision by the United States Court of Appeals for the Federal Circuit (in 2006). Multiple factual issues for both the '893 and the '995 Patents were litigated as between Ranbaxy and Pfizer.[18]

217. Two features of the district court proceedings are noted here.

218. First, in pre-trial proceedings Pfizer attempted to amend its complaint to add new patent infringement claims based on the Process Patents. However, process patents may not be

[18] Among the numerous issues litigated before the district court in the jury-waived trial between Ranbaxy and Pfizer was the early form of the evidence adduced by Ranbaxy regarding Warner-Lambert's inequitable conduct in the procurement of the '995 Enantiomer Patent. On that record, which did not include much of the evidence now available, and as between those parties, Pfizer prevailed. Of course, Plaintiff in this action and the proposed Class were not parties to that litigation and are not bound by any of the determinations made therein. The issue of Warner-Lambert's representations regarding the biological activity of the R-trans enantiomer as compared to its racemate has also been litigated in other fora worldwide. There, when addressed on a more fully developed record, Pfizer lost on the issues relating to the integrity of the "surprising" data for the enantiomer.

listed in the Orange Book and, therefore, could not serve as a basis for Pfizer's infringement action against Ranbaxy under the Hatch-Waxman Amendments. Accordingly, the district court denied Pfizer's motion because claims under these two Process Patents would be "premature."

219. Second, while the issues regarding Warner-Lambert's inequitable misconduct were hotly contested, they were also buried during the Ranbaxy trial with numerous other challenges raised by Ranbaxy against both the '995 and the '893 Patents.

220. Eventually, the district court relied on the '995 misrepresentations and the record made during that trial to rule that Warner-Lambert's PTO submissions regarding the alleged tenfold biologic power of the enantiomer over the racemate were not made with intent to deceive. The district court rejected all challenges to the validity and enforceability of both the '893 and '995 Patents.

221. Because the '995 Patent was fraudulently procured by Pfizer, and because Pfizer withheld material facts from the district court, the Ranbaxy case as to the '995 Patent was an objectively baseless sham, and was interposed merely to interfere with Ranbaxy's ability to market generic Lipitor in competition with Pfizer.

222. Ranbaxy challenged both rulings on multiple bases in an appeal to the Federal Circuit.

223. On November 2, 2006, the Federal Circuit affirmed the ruling that the '893 Patent was valid and would be infringed by Ranbaxy's product. However, the Federal Circuit reversed the district court's ruling regarding the validity of the '995 Patent, determining that claim 6—the only claim that Pfizer claimed Ranbaxy's ANDA product infringed—was invalid under 35 U.S.C. § 112, ¶ 4 for improper dependent claim structure.[19] Because this ruling rendered moot the need

[19] The Federal Circuit ruled that as a dependent claim, Claim 6 ostensibly narrowed Claim 2 by claiming "the hemi-calcium salt of the compound of Claim 2." However, Claim 2 itself was a dependent claim limited only to atorvastatin acid and did not include salts. Thus, Claim 2 and

to address other challenges to the '995 Patent, the Federal Circuit refused to address Ranbaxy's challenge to the district court's rulings relating to unenforceability for inequitable misconduct relating to the misrepresentations of the enantiomer data to the PTO. Ranbaxy thereby retained the ability to make this challenge again should the need arise.

224. Based upon the Federal Circuit's mandate in late 2006, the district court amended its final judgment order to enjoin the effective date of any approval of Ranbaxy's ANDA for generic Lipitor until March 24, 2010 (the expiry of the '893 Patent) and to remove from its final judgment order any prohibition of effective FDA approval of Ranbaxy's ANDA based on the '995 Patent. The district court's final judgment order, as amended, was sent to FDA.

225. In summary, after the entry of the final judgment in the *Ranbaxy* matter in late 2006, (i) Ranbaxy would need to await until expiry of the '893 Patent in March of 2010 before launching its atorvastatin calcium generic, (ii) there *was no '995 Patent* blocking Ranbaxy as it had been declared invalid after a final judgment, and thus there was no preclusive effect from it, and (iii) if the issue arose, Ranbaxy could still attack Warner-Lambert's misrepresentations regarding the purported surprising effects of the atorvastatin enantiomer over its racemate.

I. 2005: Pfizer files a baseless "citizen petition," intended to hinder ANDA approvals, which confirms its knowledge that Ranbaxy planned to use an amorphous formulation

226. Pfizer also sought to use a citizen petition to delay generic atorvastatin.

227. During the 30-month period from early 2003 until about August of 2005, the *Ranbaxy* litigation had stayed final FDA approval of Ranbaxy's generic Lipitor ANDA.

228. As August of 2005 approached, Ranbaxy's ANDA was the only pending ANDA on file for generic Lipitor. Pfizer knew that after the end of the 30-month stay (in August 2005), the

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Claim 6 dealt with "non-overlapping subject matter," and the claims had been improperly constructed. As a result, the 2006 Federal Circuit ruling held Claim 6 invalid.

FDA could issue final approval for Ranbaxy's generic Lipitor ANDA, which in turn would permit generic Lipitor competition to begin. Pfizer also knew that as a matter of procedure and practice, the FDA did not issue tentative approvals to ANDA filers after an applicable 30-month stay had expired; it issued final approvals only. So Pfizer would have no warning of when the ANDA approval might occur.

229. Pfizer wanted to delay such final approval for as long as it could.

230. As a result, beginning in July of 2005, Pfizer sent a series of communications, including a "citizen petition," to the FDA. Both the timing and content of these submissions were a sham, sent not for a proper purpose but as an attempt to slow down the FDA approval process for Ranbaxy's ANDA.

231. Salts of atorvastatin are polymorphic. The polymorphs can be either crystalline or amorphous. Crystalline forms have different arrangements and/or conformations of the molecules in the crystal lattice. Amorphous forms consist of disordered arrangements of molecules that do not possess a distinguishable crystal lattice. The FDA has a long history of established policies as to how to address polymorphs in the ANDA review and bioequivalence context.

232. In July of 2005, Pfizer sent a letter entitled "Generic Versions of Atorvastatin" to the FDA. In it, Pfizer said it was "concerned" that ANDA applicants for generic Lipitor were using amorphous atorvastatin calcium, which, Pfizer claimed, "may be susceptible to higher levels of impurities than are found in Lipitor and that may degrade more quickly and thus have inferior stability compared to Lipitor." Pfizer said that this "may raise questions about the approval of" ANDAs for generic Lipitor. Pfizer asked the FDA to "carefully scrutinize" such "potential differences in quality . . . before the atorvastatin variants are approved under ANDAs." Pfizer

said that "the risk of reduced quality in the generic product," due to the use of amorphous atorvastatin, was "clear," and that Ranbaxy's ANDA should be "reviewed with considerable skepticism." On November 7, 2005, Pfizer re-filed the July 2005 letter as a citizen petition, reiterating its requests.

233. In making these arguments to the FDA, Pfizer ignored more than a decade of FDA policy, the FDA's 2002 rejection of a similar argument in relation to the drug Ceftin, subsequent FDA pronouncements reinforcing that the polymorphic form of the drug (*i.e.*, crystalline versus amorphous) was immaterial to ANDA approval, and Pfizer's own clinical studies using amorphous atorvastatin to support the safety and efficacy of Lipitor. Pfizer knew, from its own work with atorvastatin and more than a decade of FDA policy, that the amorphous form of atorvastatin actually presented fewer concerns for the safety of patients than the crystalline form.

234. Pfizer itself used amorphous atorvastatin calcium for virtually all development activities for Lipitor, including numerous studies. Thus, while the Petition suggested that amorphous formulations should be looked at with considerable skepticism because they may be less pure and less stable than Lipitor (the drug substance of which was comprised of a crystalline formulation), Pfizer knew that safe and stable versions of atorvastatin calcium could be—and had been—made using the types of amorphous formulations that the generic manufacturers would use.

235. Around 1995, late in the clinical development and FDA approval processes and prior to commercially marketing Lipitor, Pfizer decided to switch to the crystalline form of atorvastatin calcium for the product it would ultimately market. However, Pfizer did so unilaterally and of its own accord, not at the request of the FDA or due to any FDA concerns. On information and belief, Pfizer did not switch from the amorphous formulations it had been using

for years based on concerns that the amorphous formulations were unsafe, ineffective, or incapable of meeting FDA requirements regarding impurities or stability. Rather, Pfizer did so in anticipation of the issuance of the '156 Patent, which claimed crystalline forms of atorvastatin.

236. Thus, because Pfizer had thoroughly studied the amorphous form, in or around June 1995, it knew and therefore told the FDA that there were no clinical safety or efficacy implications related to using the amorphous, as compared with the crystalline, form. Indeed, it turned out that toxicity was a concern for the *crystalline* form of atorvastatin calcium that Pfizer ultimately used, not the amorphous form that Pfizer abandoned and Ranbaxy proposed to use.

237. Pfizer also knew, from the *Ranbaxy* litigation, that Ranbaxy's ANDA proposed that its generic Lipitor use amorphous atorvastatin calcium as its active pharmaceutical ingredient. This knowledge was important because Pfizer later sued Ranbaxy in the Process Patent litigation, alleging infringement of process patents involving the dissolution of *crystalline Form I atorvastatin*.

238. Pfizer submitted no evidence to the FDA demonstrating that Ranbaxy's ANDA product, because it used amorphous atorvastatin calcium as the drug substance (i) would not be pharmaceutically equivalent or bioequivalent to branded Lipitor, (ii) would not demonstrate satisfaction of the conditions for approval under the FDCA, or (iii) would not be capable of being processed or manufactured under current good manufacturing practices ("cGMP").

239. Pfizer, instead, submitted its petition in contradiction to the FDA's prior stated positions concerning polymorphism.

240. In 1992, approximately thirteen years before Pfizer submitted its petition, the FDA specifically rejected a regulatory proposal that would have required an ANDA applicant to show that the active ingredient (*i.e.*, the drug substance) in its generic drug product and the active

ingredient in the corresponding brand drug "exhibit the same physical and chemical characteristics, that no additional residues or impurities can result from the different manufacture or synthesis process, and that the stereochemistry characteristics and solid state forms of the drug have not been altered" (the "1992 Regulatory Rejection"). Thus, more than a decade earlier, the FDA had already determined that differences in drug substance polymorphic forms, including differences in residues and impurities, do not cause drug substances to be considered different active ingredients for the purposes of ANDA approvals within the meaning of the FDCA and FDA regulations.

241. In fact, Pfizer had actual and/or constructive knowledge of a February 15, 2002 publicly-available denial of another company's citizen petition (the "2002 Decision"). In that decision, the FDA stated that the "FDA's view is that the [FDCA], existing regulations, preamble statements, and the FDA publication *Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book)* [already] provide an adequate basis to guide the Agency's decision-making on ANDAs seeking approval of a generic drug product whose active ingredient has a different physical form than the active ingredient in the reference listed drug." The generic ANDA filer in the 2002 Decision was, as here, Ranbaxy. Thus, more than three years before Pfizer sent its letter to the FDA, the FDA had already declined to utilize special or additional scrutiny or specifications when reviewing ANDAs for drug products that utilized different polymorphic forms of the active pharmaceutical ingredient.

242. In its 2002 Decision, the FDA expressly declined to apply special or additional scrutiny or specifications to the review of an ANDA when a different form of the active pharmaceutical ingredient was used by the proposed ANDA product. Specifically, the FDA ruled that its "review of any ANDA [already] includes ensuring that the ANDA applicant has the

appropriate controls in place with respect to the drug substance and drug product. In FDA's view, Ranbaxy has appropriate controls with respect to the drug substance and the drug product."

243. In the 2002 Decision, the FDA explained that under existing FDA standards, what mattered in connection with ANDA approval was the performance of the drug product (not the active ingredient (*i.e.*, the drug substance in isolation)):

> If a polymorph displays different properties such as melting point, solubility, and stability, these characteristics could ultimately have an impact on the approval of an ANDA for a proposed generic drug product. These characteristics could ultimately affect the approval because the approval is based not only on whether the active ingredient in the proposed generic drug product is the "same" as the active ingredient in the reference listed drug, but also on whether the proposed generic drug product is the same as the reference listed drug. FDA will approve a generic drug product if the ANDA applicant provides, among other things, sufficient information to show that the generic drug product is the "same" as the reference listed drug. However, if the active ingredient of a proposed generic drug product were to have a different polymorphic form than the active ingredient in the reference listed drug, and this difference affected the behavior or certain characteristics of the drug product, then FDA might not approve the generic drug product, despite the fact that the proposed generic drug product contained the same active ingredient as the reference listed drug.

244. In the 2002 Decision FDA also announced that:

a. "[a] difference in the physical form of an active ingredient in a generic drug product from the physical form of the active ingredient in the reference listed drug, including a difference in the crystalline structure of the active ingredient, does not bar the approval of a proposed generic drug product";

b. "[f]or a generic drug product to be regarded as having the same active ingredient under [21 C.F.R] § 314.92(a)(1), the drug substance in a proposed generic drug product need not have the same physical form as the drug substance in the reference listed drug"; and

c. "FDA's scientific expertise and experience have shown that a difference in the physical form of the active ingredient in a generic drug product from the physical form of the

> active ingredient in the reference listed drug, including a difference in the crystalline structure of the active ingredient, does not prevent a finding of therapeutic equivalence."

245. Indeed, preeminent scientists within the FDA's Center for Drug Evaluation and Research were publicly stating, since at the latest 2003, that there was "no scientific basis" upon which to conclude that an ANDA applicant's use of a different drug substance polymorph, compared with the corresponding brand drug, would prevent the ANDA applicant from demonstrating drug product bioequivalence, stability, and manufacturability. At or around the same time, those same FDA scientists also stated that there was "no scientific or regulatory basis" for requiring a generic drug product to use the same polymorphic form as the innovator.

246. At or around the same time, those same FDA scientists also stated that despite the potential effect that polymorphism may have on drug stability, "drug product stability is affected by a multitude of other factors, including formulation, manufacturing process, and packaging." As a result, they explained that "it is the stability of the drug product, not the drug substance that is the most relevant measure of drug quality." Thus, according to the FDA, existing FDA scrutiny of ANDAs was sufficient when polymorphic forms of drug substances were involved. The FDA scientist said, "under cGMPs, the sponsor of the ANDA must still provide evidence of manufacturing process validation and demonstrate that the drug product can be manufactured reproducibly, while meeting all the required in-process, release, and stability specifications."

247. In draft Guidance issued in December 2004 (the "2004 Polymorph Draft Guidance"), the FDA explained that existing FDA regulations and ANDA review procedures already accounted for polymorphism:

> In addition to meeting the standards for identity, each ANDA applicant is required to demonstrate that, among other things, the drug product exhibits sufficient stability and is bioequivalent to the [corresponding brand drug]. While the polymorphic form can affect drug product stability and bioequivalence, these

> performance characteristics are also dependent on the formulation, the manufacturing process, and other physicochemical properties (e.g., particle size, moisture) of both the drug substance and formulation excipients. Using a drug substance polymorphic form that is different from that of the [corresponding brand drug] may not preclude an ANDA applicant from formulating a generic drug product that exhibits bioequivalence and stability, and the drug substance in the generic drug product need not have the same polymorphic form as the drug substance in the [corresponding brand drug].

248. Thus, in its 2004 Polymorph Draft Guidance, the FDA reiterated what the FDA scientists had said in 2003: "because drug product stability is affected by a multitude of other factors, including formulation, manufacturing process, and packaging, it is the stability of the drug product, and not stability of the drug substance polymorphic form that should be the most relevant measure of drug quality."

249. Pfizer did not comment on the 2004 Polymorph Draft Guidance, despite being given the opportunity to do so.

250. The preface to the Orange Book provided that "[a]nhydrous and hydrated entities, as well as different polymorphs, are considered pharmaceutical equivalents," and did so at all relevant times.

251. Prior to sending its July 2008 letter and petition to the FDA, Pfizer had actual and/or constructive knowledge of the FDA's foregoing expressed views regarding polymorphic forms of active pharmaceutical ingredients.

252. The letter and Petition were interposed solely to create an obstacle to the final FDA approval of Ranbaxy's generic Lipitor ANDA. No objectively reasonable petitioner would have expected success on the merits of Pfizer's July 28, 2005 letter or its November 7, 2005 petition. Pfizer's letter and petition lacked any reasonable regulatory, scientific, medical, or other rational basis. Pfizer's letter and petition lacked any evidence that provided support to its assertions or that reflected on the approvability of Ranbaxy's ANDA product. Pfizer's letter and petition had

no possibility of affecting FDA policy or procedure. Indeed, Pfizer's letter and petition were flatly contrary to the FDA's expressed views regarding drug substance polymorphic forms, and did not reasonably argue, or argue at all, for a change in those expressed views. In short, Pfizer's letter and petition were nothing more than a thinly-veiled effort to delay the FDA from granting final ANDA approval for Ranbaxy's product.

253. Pfizer's citizen petition, which was ultimately denied on November 30, 2011, was still pending at the time Pfizer and Ranbaxy entered the Delay Agreement. As alleged below, the FDA has a practice of not addressing a citizen petition unless approval of an ANDA is imminent. Therefore, if the Ranbaxy Delay Agreement had not been reached, the FDA, under its practices and procedures, would have denied the citizen petition earlier, when Ranbaxy's ANDA was otherwise approvable.

254. The FDA denied Pfizer's petition because ANDA applicants need not show that the active ingredients in their drugs have no additional residues, impurities, or solid state forms relative to the active ingredient in the corresponding brand drug. The basis for the denial was not surprising given that it was in line with what the FDA had already stated in the 1992 Regulatory Rejection, the 2002 Decision, the 2004 Polymorph Draft Guidance, and repeatedly thereafter.

255. As the FDA has stated repeatedly before, the FDA's existing policies and procedures were adequate to identify any ANDA product which used different polymorphs than the corresponding brand product, determine whether that difference resulted in any differences in measures such as purity or stability, and, if such differences existed, whether the purity and stability data for the ANDA product satisfied the FDA's longstanding standards for such measures. Nothing about this process required any additional skepticism or special consideration

by the FDA. Accordingly, the FDA again expressly declined to apply special or additional scrutiny or specifications to the review of such ANDAs:

> We believe that the Agency's existing recommendations to industry on assessing active ingredient sameness and stability of polymorphic forms of drug substances, as well as those on comprehensive chemistry, manufacturing, and controls (CMC) and impurities, are adequate to enable an ANDA applicant to address any potential drug product stability, degradation, and impurity issues associated with the amorphous form of atorvastatin. We also believe that the Agency's existing policies and review practices are sufficient for a critical evaluation of the variables that have the potential to affect drug product quality of drug products containing amorphous atorvastatin**.**
>
> * * *
>
> In the preamble to the final rule implementing the generic drug approval provisions of the Hatch Waxman Amendments, FDA specifically rejected the suggestion that the Agency adopt a requirement that active ingredients "exhibit the same physical and chemical characteristics, that no additional residues or impurities can result from the different manufacture or synthesis process; and that the stereochemistry characteristics and solid state forms of the drug have not been altered."

256. Moreover, the FDA again stated in denying Pfizer's Petition, just as it had done in the 2004 Draft Polymorph Guidance, that "**the inherent stability of the *drug substance* polymorphic form should not be the primary consideration in making a determination of *product* stability. Rather, the stability of the generic atorvastatin drug *product* is the most relevant measure of drug product quality**" (Emphasis in original).

257. Pfizer's petition was flatly contrary to, and willfully ignored, the FDA's previous decisions and previously-expressed views in the 1992 Regulatory Rejection, the 2002 Decision, the 2004 Polymorph Draft Guidance, and repeatedly thereafter. Pfizer had no objectively reasonable basis to file the letter or petition, given those previous FDA decisions and previously expressed views.

J. Pfizer Files Sham Litigation Against Teva Based on the '995 Patent

258. On April 24, 2007, Teva Pharmaceuticals USA, Inc. ("Teva") notified Pfizer, pursuant to the Hatch-Waxman Amendments, that it had filed ANDA 78-773 seeking approval to sell a generic version of Lipitor. Teva included a Paragraph IV certification that the '995 Enantiomer Patent was invalid, unenforceable, or would not be infringed by Teva's proposed generic product.

259. On June 7, 2007, though it knew the '995 Patent was invalid and/or unenforceable, Pfizer responded by filing an action against Teva in the United States District Court for the District of Delaware, alleging infringement of the '995 Patent (excepting claim 6). The parties reached a settlement of this action on July 15, 2009, whereby, upon information and belief, Pfizer gave substantial consideration to Teva in exchange for Teva's agreement to not seek approval for its generic product for a certain period of time.

260. But for Warner-Lambert's fraudulent procurement of the '995 Enantiomer Patent and the parties' reverse payment agreement, Teva would have entered the market for generic atorvastatin calcium in or about September 2010 (the month in which Ranbaxy's period of generic market exclusivity would have expired had it entered the market upon the expiration of the '893 Patent) or earlier.

K. Pfizer Files Sham Litigation Against Cobalt Based on the '995 Patent

261. At some time prior to December 2007, Cobalt Pharmaceuticals Inc. ("Cobalt") notified Pfizer, pursuant to the Hatch-Waxman Amendments, of its application seeking FDA approval to market atorvastatin and its Paragraph IV certification that the '995 Enantiomer Patent was invalid, unenforceable, or would not be infringed by Cobalt's proposed generic product.

262. On December 6, 2007, though it knew the '995 Patent was invalid and/or unenforceable, Pfizer filed an action against Cobalt in the United States District Court for the District of Delaware, alleging infringement of the '995 Enantiomer Patent (excepting claim 6). In consenting to judgment on May 15, 2008, Cobalt admitted that the '995 Patent would be infringed by the product proposed in its ANDA. The consent also restricted the effective date of any approval of Cobalt's ANDA to be no earlier than the expiration of the '995 Patent. Upon information and belief, Pfizer gave substantial consideration to Cobalt, including the exclusive right to sell an "authorized generic" upon market entry of other generics, in exchange for Cobalt's agreement to not seek approval for its generic product for a specified period of time.

263. In 2009, Watson Pharmaceuticals acquired Cobalt and the right to market Pfizer's "authorized generic" version of Lipitor.

264. But for Warner-Lambert's fraudulent procurement of '995 Enantiomer Patent and the parties' reverse payment agreement, Cobalt (or its acquirer, Watson) would have launched a generic formulation of atorvastatin calcium in or about September 2010 (the month in which Ranbaxy's period of generic market exclusivity would have expired had it entered the market upon the expiration of the '893 Patent) or earlier.

L. 2007-2008: Pfizer begins reissuance proceedings for the enantiomer patent

265. In January 2007, and in the wake of the 2006 Federal Circuit ruling tossing the vital Claim 6 of the '995 Patent, Pfizer sought reissuance of the enantiomer patent to, in Pfizer's words, "correct a technical defect in some of the patent claims." In so doing, Pfizer sought to limit the PTO's review to a determination of whether the newly proposed re-wording of the claims (to correctly construct dependent or independent claims) would satisfy 35 U.S.C. § 112, ¶ 4.

266. While at the outset Pfizer sought only to correct what it termed a technical defect, it knew that huge problems lurked behind the scenes for a re-issuance effort. The PTO or others might raise the far more substantive problem that an enantiomer patent was simply an obvious extension of the original '893 Patent (and that the data to support a finding of surprising or unexpected activity of the enantiomer was false). By this time (early 2007), the enantiomer patent and its nearly identical foreign counterparts had been the subject of considerable litigation, not only in the *Ranbaxy* litigation (where the ruling regarding the enantiomer patent had not seen appellate scrutiny), but also in other countries throughout the world. Through these foreign proceedings, Pfizer learned it could no longer get away with relying upon the erroneous biological data to support a claim that the r-trans enantiomer of atorvastatin was ten times more active than racemic atorvastatin (or indeed that it was anything other than the expected double strength). As a result, Pfizer told the PTO that it learned that the 1989-1993 biological data contained "significant errors," and was withdrawing reference to such data as a basis to reissue the '995 Patent.

267. Throughout the reissuance proceedings, Pfizer eschewed all reliance on biologic data (including CSI data), at one point explicitly acknowledging that the biologic data originally used to support patentability was "inaccurate." Pfizer argued instead that Lipitor was entitled to additional protection under the '995 Patent because of Lipitor's overwhelming commercial success.

The re-issuance proceedings show that the biologic data could not support a basis to issue the '995 Patent

268. On January 16, 2007, Roth and Pfizer submitted the '995 reissue application. The applicants did not amend or modify the '995 Patent specification as part of the reissue proceedings. Roth's remarks include a list of the "objective evidence" that "completely refutes

any suggestion of obviousness." But now, the list does not include the purported surprising effectiveness of the R-trans enantiomer or a purported ten times greater activity of the R-trans enantiomer than the racemate.

269. An Informational Disclosure Statement of the same date states:

> Subsequent to the Federal Circuit's decision, while preparing for trial in Australia on a '995 counterpart, Pfizer first learned of *significant errors* in the COR results which neither Pfizer nor the parties adverse to it had discovered before. This discovery led Pfizer to advise the Federal Circuit that COR data could not be relied on to compare the relative activity of compounds — see Exhibit 9, page 10, fn 2. Thus *any earlier reference in Pfizer's findings, conclusions and brief to relative activity among compounds based on the COR test is withdrawn and is not relied on in these reissue proceedings. Pfizer does not at this point in the reissue rely for patentability on any comparisons based on CSI*. Neither CSI nor COR data were relied on by either U.S. court in reaching their decisions regarding the validity of '995 claim 6.

Elsewhere Pfizer states "Pfizer does not now rely on any . . . data [comparing between and among calcium salts and other salts of atorvastatin and its racemates] in support of patentability."

270. In May 2007, Ranbaxy filed a protest with the PTO against Pfizer's reissue application. Ranbaxy would continue protesting for about another year until, pursuant to a comprehensive agreement to be discussed below (the Ranbaxy Delay Agreement), its silence was bought off.

271. On June 7, 2007, as part of the enantiomer reissue proceedings, Pfizer submitted a Second Informational Disclosure Statement that discusses "Foreign Proceedings on '995 Counterparts" and attached additional materials produced as part of certain non-U.S. proceedings. Pfizer acknowledged that the biological data submitted in support of its patent applications—in the CSI Table, the Roth Declaration, and the foreign " '995 counterparts"—is inaccurate:

> [A]pplicant is submitting these documents to permit the Examiner to consider their potential materiality. Further, many of these documents . . . contain biological data or summaries of biological data, and *some of that biological data*

> *is now understood to be inaccurate* (due to transcription errors, calculation errors, experimental errors, etc.).

272. Elsewhere in the reissue proceedings, Pfizer referred to the biological data at issue in the Australian and Canadian patent litigation as "biologic data that Pfizer then argued showed that the atorvastatin enantiomer had unexpected and surprising inhibition of cholesterol biosynthesis in-vitro in comparison to the racemic form of atorvastatin," while reiterating that they "are not relying on any of the biological data as a basis for the patentability of the pending claims at the present time." Similarly, Roth and Pfizer stated, "[a]pplicant is not submitting corrected biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability."

273. At one point in the reissue proceedings, the examiner, seeing Roth's late 1980s misrepresentations in the PTO record, relied on the biological data to overcome an obviousness rejection:

> Claims 6, 13 and 14 have not been rejected as being obvious as the declaration of Bruce D. Roth filed February 25, 1991 discloses unexpected properties which would overcome any 35 USC 103(a) rejection of claims 6, 13 and 14 as atorvastatin calcium was shown to have activity greater than fifty-fold more than that of the S-trans and at least ten-fold more than that of the racemate.

274. Pfizer knew it could no longer allow the PTO to use its erroneous biological data. As a result, it "reiterated [to the PTO] that they are not presently relying on any of the biological data (including the data contained in the Roth declaration) as support for the patentability of claims 6, 13 and 14." Pfizer stated:

> Although applicant believes that the evidence provided in the Roth Declaration is sound, and is in no way disclaiming this data, it does not believe that it is necessary to consider such evidence in view of the present record . . . applicant respectfully requests that the Examiner withdraw her reliance on the data in the

> Roth Declaration and focus instead on the overwhelming evidence of secondary considerations that are discussed above….

The referenced secondary considerations include the argument based on Lipitor's subsequent commercial success. But Pfizer's commercial success argument was no more viable as support for reissuance of the '995 Enantiomer Patent than Warner-Lambert's "surprising activity" argument was during the initial application process.

275. In August 2007, the PTO issued a First Office Action rejecting Pfizer's reissue application on grounds set forth in Ranbaxy's May 2007 protest—that certain claims in the '995 Patent were anticipated, obvious, or constituted double-patenting.

276. On April 24, 2008, the PTO issued a non-final *rejection* of claims 6, 13, and 14. In so doing, the examiner stated, "[a]s the data contained in the Roth declaration has not been relied on by Applicant in the instant reissue and is not a comparison of the claimed subject matter (atorvastatin calcium) to the closest prior art, the examiner withdraws the reliance on the data in the Roth Declaration to overcome an obviousness rejection of reissue claims 6, 13 and 14."

277. On April 6, 2009, after the Delay Agreement was established and Ranbaxy ceased protesting reissuance of the '995 Patent, the PTO reissued claims 6, 13, and 14 of the '995 Patent as the '667 Patent. The reissued patent retained the same expiration date.

Pfizer Faced the Real Risk that its Application to Reissue the '995 Patent Would Be Denied

278. As Pfizer could no longer rely on the erroneous data that was submitted in connection with the '995 Patent application, Pfizer faced the real risk that its application to reissue the '995 Patent would be denied.

279. Pfizer's arguments for reissuance were extremely weak. Instead of addressing the pertinent question of whether the '995 R-trans enantiomer patent was obvious given the coverage for atorvastatin already in the original '893 compound patent—*i.e.*, whether the enantiomer has

some surprising and unexpected attributes beyond those of the racemic compound—Pfizer's reissue application repeatedly characterized the question before the PTO as whether "Lipitor" had experienced commercial success warranting, as a secondary consideration, a conclusion that it was non-obvious. Pfizer's 2007 reissue application and its later support read more like promotional pieces to sell the PTO on Lipitor's marketing success, rather than support for Pfizer's position on the actual issues to be decided by the PTO.

280. But Pfizer knew that this argument of looking generally at "Lipitor" (rather than distinguishing attributes of the enantiomer that were surprising and unexpected) was a deception. Pfizer knew that Lipitor was protected by the '893 Patent from its initial launch through all of the re-issue proceedings. Thus, any showing of success of Lipitor generally would not in any way elucidate why the '995 Patent (which *also* covered Lipitor) was not obvious over the original '893 compound patent.

281. Indeed, Warner-Lambert, and later Pfizer, repeatedly identified the '893 Patent as the patent that would provide protection for Lipitor. Warner-Lambert listed the '893 Patent in the Orange Book, thus forcing generic companies to serve a Paragraph IV certification if they wished to launch a generic before expiry of the '893 Patent. Shortly after Lipitor was approved by the FDA in late 1996, Warner-Lambert sought, and obtained, a patent extension on the '893 Patent (not the '995 Patent) to make up for years that it took to study Lipitor. And Pfizer later brought infringement cases against generic companies arguing that their proposed Lipitor products would infringe the '893 Patent.

282. Put simply, from late 1996 to 2009, Pfizer's commercialization of Lipitor was actively protected by both the original '893 Lipitor compound patent and the '995 Patent, *i.e.*, both patents covered the commercialized R-trans enantiomer calcium salt formulation. Thus, any

arguments raised with the PTO at any time regarding the commercial success of "Lipitor" could not, as a matter of fact or law, elucidate in any way whatsoever whether or not the '995 Patent was non-obvious over the '893 Patent.[20]

283. Outside of the '995 reissue proceedings, Pfizer has admitted that commercial success of Lipitor cannot be used as a basis to distinguish between the '893 and '995 Patents. According to Pfizer it would not be appropriate "to infer the non-obviousness of *two* unrelated patents based on the success of a *single* commercial product." (Emphasis in original.)

284. By April of 2008, things looked bleak, as they should have, for reissuance of an enantiomer patent. The PTO had repeatedly rejected the application; since Pfizer was no longer relying upon the false biological data, the PTO had before it no scientific basis to conclude the enantiomer claims were anything other than obvious over the '893 Patent; Pfizer had repeatedly argued "commercial success," but that basis for allowance was a logical impossibility, and Ranbaxy remained as an objector to re-issuance in the proceedings, effectively blocking any reissuance.

M. The circumstances in early 2008 leading to the Ranbaxy Delay Agreement

285. By 2008, Pfizer faced the real risk that generic entry could occur in or around March of 2010. After all, (i) the basic compound patent for Lipitor, the '893 Patent, afforded Pfizer

[20] Pfizer's re-issue efforts misleadingly led the examiner not to appreciate this point. For example, Pfizer's reissue application stated that the re-wording of the '995 Patent should be allowed so that the "active ingredient responsible for Lipitor's success [could] be restored and the active ingredient that makes Lipitor work will again be protected by species claims," falsely suggesting that without the allowance Lipitor would be without patent protection. This was a false suggestion because Lipitor's active ingredient was also covered by the original '893 Patent. Similarly, Pfizer's reissue application misleadingly referred only to the portion of the 1993 ruling of the board of appeals decision which held the '995 Patent not anticipated by the '893 Patent; Pfizer completely ignored the portion of that same ruling which determined that an enantiomer patent under circumstances such as this case would be obvious over an original compound patent. Elsewhere, Pfizer stated that "one molecule - the molecule specifically claimed in Claim 6 of this re-issue application is responsible for the success."

protection only until March of 2010; (ii) the '995 Patent had been adjudicated, with finality, as invalid and therefore could not be used to extend exclusivity beyond March of 2010; (iii) its effort to gain re-issuance of an enantiomer patent had been met with successful protests by Ranbaxy, rejections by the PTO, and the need for Pfizer to eschew any reliance on the bogus scientific data originally used to get the patent; (iv) even if a re-issuance application were allowed, any re-issued enantiomer patent could still be challenged by Ranbaxy; (v) its two Process Patents could not apply to Ranbaxy's product (and would likely not apply to other generic versions either) and did not provide Pfizer with any regulatory exclusivities such as additional 30-month stays; (vi) its two Unasserted Stabilization Formulation Patents had never been, and could never be, asserted against Ranbaxy (and likely any other generic company); and (vii) the petition it had filed with FDA lacked all merit and would, in time, be rejected.

The '893 Patent could only bar generic entry until March of 2010, and Pfizer faced the risk that reissuance of the '995 Patent would be denied.

286. As to the '893 Patent, the *Ranbaxy* district court's entry of final judgment in the end of 2006 barred generic entry by Ranbaxy until March of 2010. As to the '995 Patent, however, the final order adjudged claim 6 (the only '995 Patent claim asserted against Ranbaxy) invalid for improper dependent claim structure. As a result, the '995 Patent could not, as a matter of law, be enforced against Ranbaxy. When in early 2008 Pfizer looked at its strategic options, it could only expect the '893 Patent to bar generic entry by Ranbaxy until March of 2010 (with the '995 Patent having no preclusive effect). After March of 2010, the FDA could have granted final approval of Ranbaxy's ANDA. Even if the '995 Patent was reissued, it would not automatically bar Ranbaxy. Pfizer would need to obtain a preliminary injunction or court ruling of validity and infringement.

287. As to the '995 Patent, during the re-issuance proceedings and given Ranbaxy's protest to it, Pfizer could no longer use the corrupt and rigged data (which misleadingly showed a ten-fold increase in biologic activity of the enantiomer over the racemate), that it had used to obtain the '995 Patent in the first place. Pfizer's arguments for reissuance were also extremely weak and would have failed had Ranbaxy continued to play an adversarial role in the proceedings.

The two Unasserted Stabilization Formulation Patents and the '156 Patent could not bar Ranbaxy's entry.

288. In 2008 when assessing strategic options, Pfizer could gain no solace from its two Unasserted Stabilization Formulation Patents (*i.e.*, the '971 and '104 Patents), nor the '156 Patent, as methods to preclude Ranbaxy entry.

289. As to the two Unasserted Stabilization Formulation Patents, neither patent had yet been used as the basis for an infringement action against Ranbaxy, nor could they. Both patents were for narrow formulations to achieve stabilization for particular atorvastatin drug products, and thus did not apply to Ranbaxy's proposed product under its ANDA.

290. As to the '156 Patent, it covered *crystalline* forms of atorvastatin, not amorphous ones. But Ranbaxy's product was the latter. Pfizer did not and could not show that Ranbaxy's product would infringe the Unasserted Stabilization Formulation Patents or the '156 Patent, and as of today, Ranbaxy's ANDA is presumed not to infringe these patents.

As to Lipitor, the two Process Patents would not apply to Ranbaxy's (not likely to other generic companies') generic product

291. The two Process Patents also did not provide a vehicle to delay entry of Ranbaxy's generic version of Lipitor (nor could they delay entry of all or most other generic versions of other generic companies).

292. The ’511 and ’740 Patents have applications that trace back to a common application and therefore the specifications for both are virtually identical. The Summary of the Invention sections of these two patents are identical and state:

> [T]he present invention is a novel process for the preparation of amorphous atorvastatin and hydrates thereof which comprises . . . (a) dissolving *crystalline Form I atorvastatin* in a non-hydroxylic solvent; and (b) removing the solvent to afford amorphous atorvastatin

(emphasis added).

293. The Process Patents are narrow in scope. For a generic manufacturer’s process to infringe either of these patents, the generic manufacturer must, *inter alia*, dissolve *crystalline Form I atorvastatin* in the specified solvent. If the manufacturing process dissolves any crystalline structure other than Form I in the specified solvent, or dissolves amorphous atorvastatin, the process does not and cannot infringe either of the Process Patents. To infringe, the manufacturing process used must also include each and every other limitation of the claimed processes of the Process Patents. For example, Claim 1 of the ’740 Patent further requires use of “a non-hydroxylic solvent at a concentration of about 25% to about 40%.”

294. Because of the narrow scope of the Process Patents, and the ample number of both amorphous and crystalline forms of atorvastatin that were available, a very large number of non-infringing alternatives existed to the technology claimed in the Process Patents. Indeed, the prior art, including the ’893 Patent (covering the active ingredient of Lipitor, atorvastatin calcium), describes numerous processes for making atorvastatin calcium that are prior art to the Process Patents and would invalidate the claims of the Process Patents if those claims read on the processes described in the ’893 Patent.

295. During Pfizer’s own development of Lipitor, Pfizer first produced (for years) amorphous atorvastatin in its manufacturing processes before developing (much later) crystalline

formulations such as Form I. There is no need for someone seeking to produce amorphous atorvastatin calcium to first produce Form I crystalline atorvastatin calcium.

296. Pfizer knew that generic companies would design around process or formulation patents such as these, which is evident in its comment that "[t]he generic versions of atorvastatin will differ in physical form from Lipitor solely to support an effort by the generic applicants to avoid the reach of patent protection of the innovator." It is common practice for experienced generic companies such as Ranbaxy to conduct patent searches during the drug development process, and to select drugs and approaches to formulating products that are allegedly covered by patents but which the generic companies can readily design around.

297. Process patents cannot be listed in the FDA's Orange Book because they are not patents claiming an approved drug or an approved use of a drug. The existence of the Process Patents did not, therefore, provide a vehicle for immediate patent litigation nor did it create a regulatory impediment to generic entry. (ANDA filers are not required to file Paragraph IV certifications, or any other certifications, with respect to non-listed patents. As a result, no subject matter jurisdiction based on non-listed patents exists prior to actual generic entry.)

298. Nor did the existence of the Process Patents create any significant design or legal impediment to generic entry even when litigation might be ripe. The Process Patents narrowly claim only one of many different ways to manufacture amorphous atorvastatin. Numerous non-infringing alternatives to the processes claimed in the Process Patents existed such that there was no reasonable likelihood that Pfizer would be able to use the Process Patents to obtain a court order enjoining ANDA filers, including Ranbaxy, from selling generic versions of Lipitor on the ground that they infringed the Process Patents. In fact, a later Pfizer patent summarized several other processes by which one could manufacture amorphous atorvastatin. *See* U.S. Patent No.

8,258,315. Indeed, in the '315 Patent, Pfizer further noted that a number of published U.S. and International Patent Applications and patents have disclosed processes for "preparing amorphous atorvastatin." For example, "WO 01/28999 discloses a process for forming amorphous atorvastatin by recrystallization of crude atorvastatin from an organic solvent." Also, "WO 01/42209 discloses preparing amorphous atorvastatin by precipitating the atorvastatin using a solvent in which atorvastatin is insoluble or very slightly soluble, from a solution of atorvastatin which is provided with a solvent in which atorvastatin is freely soluble." Further, "U.S. Published Patent Application 2004/0024046 A1 discloses a process for forming amorphous atorvastatin by precipitating atorvastatin from a solution with a solvent in which atorvastatin is insoluble or very slightly soluble."

299. As a result, the Process Patents had no exclusionary power vis-à-vis potential generic competitors, including Ranbaxy. Pfizer did not (and could not) prove the facts necessary to meet its burden of establishing infringement of each element of the Process Patents. Therefore, even though the Process Patents were presumed to be valid and enforceable, they had no exclusionary power. Pfizer could not use the Process Patents to exclude Ranbaxy (or likely any would-be generic entrant) from the market using the Process Patents.

Pfizer faced the risk that its citizen petition could be denied at any moment

300. In early 2008, Pfizer's citizen petition related to amorphous atorvastatin calcium remained pending. While that petition would frustrate FDA processing of pending ANDAs, because it lacked any credible scientific basis, Pfizer could not expect the petition to delay FDA approval of Ranbaxy's ANDA for atorvastatin calcium any longer.

301. Instead, in circumstances where the FDA had been advised of an agreed-upon generic entry date, it would be expected that once an ANDA was otherwise ready for approval, the FDA

would deny the petition simultaneously with allowance of an ANDA on the agreed upon entry date (as a common course for the FDA is to leave a petition pending while an ANDA is not otherwise ready for approval).

As to Accupril, however, Pfizer had enormous leverage over Ranbaxy.

302. In stark contrast to the dire circumstances Pfizer found itself in early 2008 with respect to efforts to extend Lipitor exclusivity beyond March of 2010, Pfizer was sitting in the catbird seat with respect to a different blockbuster drug, Accupril. More detail will follow, but by 2008 Pfizer had established in the *Accupril I* litigation that Teva's generic Accupril product infringed Pfizer's patents. Although the Ranbaxy Delay Agreement ended the *Accupril II* litigation, Pfizer had, while the parties were still litigating the case, obtained a preliminary injunction, affirmed upon appellate review, indicating that Ranbaxy's product likely infringed Pfizer's patents as well. And the court in that case had only a few months earlier ruled that Pfizer would be permitted to press damage claims dating back to Ranbaxy's initial launch of the generic version of Accupil, with damage claims in the hundreds of millions of dollars.

303. Thus, in early 2008 Pfizer found itself in two, quite different, positions with respect to Ranbaxy. As to Lipitor, its ability to stop Lipitor, the largest selling drug of all time, from going generic sometime shortly after March of 2010 was slim. But as to Accupril, Pfizer had against Ranbaxy (its Lipitor nemesis) damage claims worth hundreds of millions of dollars.

N. Pfizer created the illusion of litigation to create the appearance of patent life beyond March of 2010

304. To stop generic competition for Lipitor, Pfizer needed a stage to disguise a reverse payment to Ranbaxy in order to buy Ranbaxy's agreement to delay launching its generic version of Lipitor. If there were a pending court case against Ranbaxy involving Lipitor, Pfizer could then settle with Ranbaxy through a reverse payment and (unlawfully) extend its Lipitor market

exclusivity and associated monopoly profits, then later try to argue that its settlement was lawful. But in early 2008 Pfizer had no litigation against Ranbaxy that it could settle.

305. So Pfizer needed to first create the illusion of litigation against Ranbaxy involving patents that applied to Lipitor. Since Pfizer wished to extend the purported patent life for Lipitor past March 24, 2010 (expiry of all exclusivities applicable to the '893 Patent), it needed the illusion of litigation involving patents with a life beyond March 24, 2010. And at this time the '995 Patent was still hung up in re-issue proceedings that looked, in part from Ranbaxy's objections, increasingly dismal. So for a basis to bring suit, Pfizer turned to the Process Patents, the '740 and '511 Patents.

306. On or about March 24, 2008, Pfizer filed a complaint in the United States District Court for the District of Delaware alleging that Ranbaxy infringed the Process Patents ("*Ranbaxy II*"). Thus, nearly five years after it first attempted to sue Ranbaxy for allegedly infringing the Process Patents, and knowing that a court had already ruled that it lacked standing under 28 U.S.C. §§ 2201 and 2208 to do so, Pfizer again sued Ranbaxy for declaratory judgment of infringement of the very same Process Patents on the very same grounds that earlier resulted in dismissal.

307. A lawsuit based on the Process Patents was not justiciable years earlier. It was less so in *Ranbaxy II*. At the conclusion of the Ranbaxy litigation, the final judgment permanently enjoined Ranbaxy from engaging in the manufacture, use, offer to sell or sale of its generic version of Lipitor until the expiration of all exclusivities applicable to the '893 Patent (March 24, 2010). There was no jurisdiction for *Ranbaxy II*. Pfizer knew this.[21]

[21] Likewise, because process patents cannot be listed in the Orange Book, Pfizer could not (and did not) use the Process Patents to obtain the automatic 30-month stay of FDA approval of a pending ANDA.

308. The *Ranbaxy II* complaint contained only the most conclusory of infringement allegations. The complaint included no factual allegations or support establishing that Ranbaxy's process satisfied the various elements of the claims of the Process Patents. The complaint did not even allege that Ranbaxy starts with the crystalline atorvastatin when making amorphous atorvastatin. Instead, it merely concludes:

> 30. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '511 patent.
>
> * * *
>
> 41. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '740 patent.

309. These allegations were not sustainable and were objectively baseless as a matter of fact and law. It was objectively clear to a reasonable litigant, and both Pfizer and Ranbaxy knew, that the Process Patents could not and would not exclude Ranbaxy from manufacturing and marketing generic Lipitor. No reasonable litigant would believe that Ranbaxy was unaware of the elements of the Process Patents or that Ranbaxy was incapable of, or unwilling to, avoid infringing the Process Patents.

310. The Process Patents narrowly claim only one of many different ways to manufacture amorphous atorvastatin. In fact, a later Pfizer patent summarized several other processes by which one could manufacture amorphous atorvastatin. *See supra* ¶ 297.

311. There were numerous forms of atorvastatin, other than the crystalline Form I specified in the Process Patents, that Ranbaxy could have (and, upon information and belief, did) use at the start of its manufacturing process. And there was no need for Ranbaxy to first create a crystalline form of atorvastatin calcium before creating an amorphous form of atorvastatin calcium.

312. Moreover, Pfizer knew that Ranbaxy intended to use amorphous atorvastatin as a starting material in manufacturing its atorvastatin calcium. Pfizer had no basis to believe that Ranbaxy would use infringing crystalline atorvastatin to achieve amorphous atorvastatin in its manufacturing. Nor did Pfizer have any reasonable expectation that during the discovery process it would learn information supporting a claim of infringement of the two Process Patents.

313. During the pendency of *Ranbaxy II*, Pfizer never produced any evidence to support its purely conclusory allegations that Ranbaxy infringed the Process Patents. Nor could it, since such allegations were false and baseless as a factual (and legal) matter.

314. On June 17, 2008 (less than three months after Pfizer filed its pretextual declaratory judgment suit based on the Process Patents), Ranbaxy and Pfizer entered into their reverse payment, market-allocating, "pay-for-delay" agreement. The parties agreed that Ranbaxy would be enjoined from engaging in the manufacture, use, or sale of generic Lipitor until November 30, 2011.

315. To disguise the Ranbaxy Delay Agreement's true anticompetitive purpose, Pfizer and Ranbaxy characterized the agreement as, in part, settling the *Ranbaxy II* litigation. That was a pretext for its true anticompetitive goals and accomplishments.

316. The Ranbaxy Delay Agreement is a reverse payment agreement constituting an unlawful contract, combination and conspiracy to allocate the entire United States market for atorvastatin calcium to Pfizer until November 30, 2011.

317. The Agreement was designed to exclude generic competition for Lipitor in the United States and enable Defendants to continue overcharging all end-payors through supracompetitive prices. As discussed more fully below, under the Delay Agreement "the party with no claim for damages"—first-filer Ranbaxy—"walk[ed] away with money simply so it w[ould] stay away

from the patentee's market," and thus unduly delayed generic competition for Lipitor. *Actavis*, 133 S. Ct. at 2233. The sheer size of Pfizer's financial inducements to Ranbaxy, the non-relation of such payments to Pfizer's anticipated future litigation costs, the direct ties between the payments and the exclusion of Ranbaxy's generic product from the United States market, and the complete lack of any convincing, justification for the reverse payments all confirm that the Agreement was anticompetitive. *See id.* at 2237.

Pfizer's Financial Inducements to Ranbaxy

318. In exchange for Ranbaxy's agreement to delay its launch of (and not to authorize another ANDA filer to launch) generic Lipitor until November 30, 2011, Pfizer gave substantial financial inducements to Ranbaxy, including: (a) Pfizer's dismissal, in exchange for a token $1 million, of hundreds of millions of dollars of likely damages claims (including claims for enhanced damages for Ranbaxy's willful infringement) stemming from Ranbaxy's "at risk" launch of a Accupril; and (b) the right to market generic Lipitor in at least eleven foreign markets outside the United States.

319. According to then-Chairman and CEO for Ranbaxy, Malvinder Mohan Singh, the Delay Agreement covered "'over 90% of the market'" for generic Lipitor and provided Ranbaxy "'huge revenue upside'" and "'revenue certainty.'"[22] Singh also characterized the Agreement as "the largest and the most comprehensive out-of-court settlement ever in the pharma industry covering a total revenue of over $13 billion," and indicated that he expected "[t]he revenues will start kicking in from [2008] as we will be launching [a] generic version of Lipitor in Canada this

[22] Bhuma Shrivastava, Susan Decker & Shannon Pettypiece, *Ranbaxy and Pfizer Settle Lipitor Lawsuit*, LIVEMINT, June 19, 2008, *available at* http://www.livemint.com/Home-Page/pVHN8nFGcuimVkiXlJ9PgO/Ranbaxy-and-Pfizer-settle-Lipitor-lawsuit.html?facet=print.

calendar year."[23] Industry estimates at the time pegged Ranbaxy's revenue upside from the Agreement for Lipitor at $1.5 billion over a four-year period up to May 2012.[24]

Pfizer's release of the *Accupril* liability was worth hundreds of millions of dollars

320. Years earlier, in late 2004, Ranbaxy (acting in partnership with the first-filer Teva) had launched at-risk a generic version of Pfizer's branded drug product Accupril—a product that had branded sales of over $500 million prior to the Ranbaxy/Teva launch. Under an agreement with Teva, Ranbaxy supplied its generic Accupril product to Teva, who was appointed the exclusive distributor of the product. But events had not gone as apparently planned, and by 2008 Ranbaxy faced huge financial exposure. To understand the basis for, and magnitude of, this exposure, some background is necessary.

321. In January 1999, Teva filed the first ANDA seeking approval to market generic Accupril. In December 2002, Ranbaxy also filed an ANDA for Accupril. The ANDAs of both companies contained paragraph IV certifications.

322. Within 45 days of receiving Teva's certification, on March 2, 1999, Pfizer filed a patent infringement suit against Teva ("*Accupril I*"). Pfizer did not respond to Ranbaxy's paragraph IV certification letter, nor did it sue Ranbaxy within forty-five days of receiving the letter, which would have triggered a 30-month stay of approval of Ranbaxy's ANDA.

323. The *Accupril I* litigation continued and in October 2003, Pfizer established on summary judgment that Teva's generic Accupril product infringed claims 1, 4-10, 12, 16, and 17 of Pfizer's '450 patent covering Accupril. *See Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 289 F. Supp. 2d 515, 520 (D.N.J. 2003). While Teva later appealed certain aspects of this ruling,

[23] *Ranbaxy, Pfizer Sign Truce Over Lipitor*, THE ECONOMIC TIMES, June 19, 2008, *available at* http://articles.economictimes.indiatimes.com/2008-06-19/news/27713209_1_lipitor-caduet-daiichi-sankyo.
[24] *Id.*

Teva never challenged the district court's determination that its generic Accupril product infringed claims 16 and 17 of the '450 patent.

324. During the course of the *Accupril I* proceedings, Pfizer and Teva had contested the meaning of the term "saccharide" as used in the '450 patent. Teva argued for a broad construction, whereas Pfizer argued for a narrow construction. Eventually, the parties entered a stipulation whereby they agreed that as used in the '450 patent, the term "saccharide" means a "sugar" and includes only lower weight molecular carbohydrates, specifically mono- and disaccharides and their simple derivatives.

325. On June 29, 2004 Judge Debevoise issued an opinion in *Accupril I* rejecting Teva's obviousness and anticipation arguments, as well as its allegations of inequitable conduct, and establishing the validity and enforceability of the '450 patent covering Accupril. *See Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, No. 99-cv-922, 2004 U.S. Dist. LEXIS 12915, (D.N.J. June 29, 2004) [ECF No. 217] at p. 6. On the same day, Judge Debevoise entered an injunction barring Teva from selling the generic quinapril product described in its ANDA. *See Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, No. 99-cv-922 (D.N.J. June 29, 2004) [ECF No. 218].

326. Meanwhile, Ranbaxy wanted to launch its generic version of Accupril, but was prevented from obtaining FDA approval due to Teva's right to 180 days of marketing exclusivity as the first-filing generic (an exclusivity that had not yet been triggered). Because Teva was enjoined from launching its own product, on August 26, 2004, unbeknownst to Pfizer, Teva and Ranbaxy entered into a distribution and supply agreement pursuant to which Teva was appointed as the exclusive distributor of *Ranbaxy's* generic Accupril product. In exchange, Teva

relinquished its 180-day exclusivity, thereby clearing the way for Ranbaxy to obtain final FDA approval.[25]

327. Under the agreement, Ranbaxy would provide Teva with its FDA-approved product for sale, with the parties splitting the profits equally. The partnership also provided that *Ranbaxy would fully indemnify Teva for any liability related to Ranbaxy's launch*. Thus, Ranbaxy would be solely responsible for any damages to Pfizer flowing from the launch of generic quinapril.

328. Ranbaxy obtained final approval of its ANDA product in December 2004 and, pursuant to this agreement, the parties engaged in a surprise launch of Ranbaxy's generic Accupril product on December 16, 2004.

329. Ranbaxy's ANDA product contained microcrystalline cellulose ("mcc"), a polysaccharide.[26] Ranbaxy contended that, in light of the positions taken by Pfizer in *Accupril I* (Pfizer argued for a narrow construction) and the stipulation entered into by the parties in that case (defining saccharide as sugar, limited to mono- and disaccharides), the mcc in its ANDA product did constitute a "sugar" and therefore did not infringe the '450 patent.

330. In January 2005, Pfizer sued Ranbaxy and Teva for patent infringement, with Judge Debevoise again presiding ("*Accupril II*"). Pfizer sought treble damages for willful infringement pursuant to 28 U.S.C. § 284. *See Etna Prods. Co., Inc. v. Q Mktg. Group, Ltd.*, 2004 U.S. Dist. LEXIS 15323, at *35, 40-41 (S.D.N.Y. Aug. 6, 2004) (Section 284 "imposes no limitation on the types of compensable harm resulting from infringement" and compensatory damages may be enhanced up to three times where an infringer has acted with deliberate intent to infringe and cause harm). Pfizer moved for, and successfully obtained, a preliminary injunction against

[25] *See generally* Ranbaxy's Statement of Material Facts, *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 05-cv-620 (D.N.J. May 8, 2006) ("*Accupril II*") [ECF No. 91] at ¶¶ 10-14.
[26] *See* Decl. of Gerald S. Brenner, Ph.D. in Support of Pls.' Mot. for a Prelim. Inj., *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 05-cv-620 (D.N.J. Feb. 14, 2005) [ECF No. 3-2] at ¶¶ 28-29.

Ranbaxy and Teva which halted all generic sales. The order was granted on the basis that Pfizer had shown a strong likelihood that it would prevail on the merits. The Court of Appeals for the Federal Circuit unanimously affirmed the district court's preliminary injunction order. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 2005 U.S. Dist. LEXIS 29050 (March 31, 2005), *aff'd*, 429 F. 3d 1364 (Fed. Cir. 2005).

331. Pfizer posted a $200 million bond in conjunction with the injunction going into effect, demonstrating that Pfizer placed great value on preserving its Accupril franchise, and it informed the court that Ranbaxy and Teva's sale of "massive quantities" of generic product had "decimated" Pfizer's Accupril sales. Pfizer had sales in 2004 of approximately $534 million for branded Accupril. In 2005, the year after Ranbaxy/Teva launched generic Accupril, Pfizer's sales of branded Accupril had declined to approximately $71 million.

332. Teva, Ranbaxy's co-defendant, informed the court that because of the previous rulings on validity and enforceability rulings in *Accupril I*, Teva would not seek to re-litigate those issues. Judge Debevoise, in discussing discovery in *Accupril II*, remarked that "[t]he liability issues have been well reviewed."

333. With respect to infringement of the '450 patent by its generic Accupril product, Ranbaxy conceded that if the court in *Accupril II* adopted the claim construction then being put forth by Pfizer—namely that as used in the '450 patent "saccharide" was *not* limited to "sugar" and encompassed polysaccharides—then it "absolutely" infringed. Judge Debeoise, in granting the preliminary injunction in *Accupril II* adopted the claim construction put forth by Pfizer. In upholding the injunction, the Federal Circuit noted:

> The district court did not clearly err in determining that Warner-Lambert is likely to prevail in its charge that Ranbaxy literally infringes claim 16. Ranbaxy conceded in the preliminary injunction hearing that its formulation 'absolutely' literally infringes claim 16 if 'saccharides' is construed to include polysaccharides.

> *Given that concession and the fact that we have construed 'saccharides' to include polysaccharides, we cannot help but conclude that the district court was on solid ground in finding that it is likely that Ranbaxy literally infringes claim 16*. . . . Ranbaxy's challenges to the district court's finding are easily rejected.

Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F. 3d 1364, 1377 (Fed. Cir. 2005) (emphasis added).

334. With respect to invalidity and unenforceability, Pfizer took the position that the issues of invalidity and unenforceability "have been decided conclusively against Teva in the first lawsuit."[27] Pfizer later described the invalidity and unenforceability defenses raised in the Teva litigation as follows:

> Throughout years of hard fought litigation, Teva asserted *every conceivable challenge* in an effort to have the '450 patent declared invalid, unenforceable and not infringed. Teva asserted the '450 patent was unenforceable for 'inequitable conduct,' that the patent was invalid for lack of novelty, nonobviousness, non-enablement and improper inventorship.[28]

All of Teva's invalidity and unenforceability arguments, however, were ultimately rejected by the district court and/or on appeal to the Federal Circuit.

335. In fact, Ranbaxy told the Court that it was relying entirely on its (rejected) noninfringement position, and did not have any invalidity or unenforceability theory prior to the preliminary injunction decision:

> Ranbaxy felt it had the silver bullet defense . . . Ranbaxy wanted to win on non-infringement. . . . Does Ranbaxy want the patent knocked out, invalidated? No, of course not. Ranbaxy doesn't care because it's got a non-infringement defense. And the preliminary injunction, your Honor, you'll recall Ranbaxy's sole argument was based on non-infringement. Do we want the patent knocked out? No.[29]

336. Meanwhile, in August 2005, in *Accupril I*, the Federal Circuit affirmed the finding of enforceability and validity of the '450 patent, except as to the enablement issue, aspects of which

[27] *Accupril II*, ECF No. 82 at 1-2.
[28] *Accupril II*, ECF No. 106 at 2 (emphasis added).
[29] Accupril Hearing (May 22, 2006) at 20:9-19 (PFE_LIP_AT_05587175).

were remanded to the district court. 418 F. 3d 1326 (Fed. Cir. 2005). On remand, the district court held that all claims were enabled. *Warner Lambert Co. v. Teva Pharms. USA, Inc.*, 2007 U.S. Dist. LEXIS 87669, at *27-28 (D.N.J. Nov. 29, 2007). Teva did not challenge on appeal the district court's grant of summary judgment for Pfizer regarding Teva's infringement of claims 16 and 17. Teva did, however, challenge certain aspects of the district court's grant of summary judgment on infringement for other claims (*i.e.*, claims 1, 4-10, and 12), which the Federal Circuit remanded to the district court. On remand, the district court granted Pfizer's motion for summary judgment on infringement as to those claims as well. 2006 U.S. Dist. LEXIS 3539 (D.N.J. Jan. 31, 2006).

337. In the *Accupril II* litigation Ranbaxy asserted that it was entitled to present different variations of the same invalidity theories (including, *inter alia*, obviousness, anticipation, and non-enablement) on which Teva had lost in *Accupril I*.

338. Ranbaxy had no reason to expect that re-litigating the same invalidity and unenforceability defenses that Teva had presented (which—unlike infringement—are not party specific) would result in a more favorable outcome.[30] For all purposes, Ranbaxy was in the challenging position where the best invalidity and unenforceability theories already had been resolved in favor of Pfizer. Accordingly, as both the district court and Federal Circuit agreed, Pfizer had established a likelihood of success on the merits of the litigation against Ranbaxy.

339. After the grant of preliminary injunction, Pfizer knew that there was "a strong likelihood that Ranbaxy will lose the liability phase of this case."[31]

[30] August 21, 2006 letter to Court, *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 05-cv-620 (D.N.J. Aug. 21, 2006) [ECF No. 107] at p. 4.
[31] *Accupril II*, ECF No. 94 at 1-2, 9 ("[T]here is already a record indicating the likelihood that liability will be decided ***against*** Ranbaxy.").

340. Pfizer also described the case as "less complicated than the norm."[32] In fact, Pfizer asserted "[w]ith the really difficult issues having been already decided during the preliminary injunction proceedings in this case, or during the seven-year pendency of the first [Teva] litigation, this case is about as simple as a patent case gets." *Id.* at 6-7.

341. As of February 2008, most of the discovery in *Accupril II* was complete.[33] The parties had served and responded to interrogatories, requests for the production of documents, and taken depositions. In fact, Ranbaxy had proposed that fact discovery conclude in February 2008.[34]

342. Ranbaxy was likely liable for hundreds of millions of dollars in damages to Pfizer.

343. In Pfizer's April 2005 Earnings Conference Call, Jeffrey Kindler (who later became Pfizer's CEO in 2006) told shareholders that:

> The court ordered Teva and Ranbaxy to immediately stop marketing the product, which Teva had launched last Dec. under its own label, but with an agreement for indemnification by Ranbaxy. The court held that we were likely to prevail in our infringement suit and ordered the injunction to prevent any further sales. We intend to proceed aggressively with that case. There has been no trial setting yet, but at trial, we intend to seek recovery for lost profits and sales that we incurred as a result of them having an infringing product on the market. We believe that is going to result in very substantial damages on our behalf and we intend to seek that form out. . . . *And as I said, we had very, very substantial damages in the way of lost profits that we intend to recover from Ranbaxy*.

(emphasis added). In other words, in line with its fiduciary responsibilities to shareholders, Pfizer told its shareholders that it would aggressively seek very substantial damages from Ranbaxy for Accupril.

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[32] *Accupril II*, ECF No. 94 at 6.
[33] Feb. 22, 2008 letter to Court, *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 05-cv-620 (D.N.J. Feb. 22, 2008) [ECF No. 181].
[34] August 21, 2006 letter to Court, *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 05-cv-620 (D.N.J. Aug. 21, 2007) [ECF No. 107] at p. 6.

344. Ranbaxy itself conceded that conclusion that "the stakes are high [is] reflected by the fact that Plaintiffs posted a $200 million bond to secure issuance of a preliminary injunction against Ranbaxy and Teva."[35]

345. Not only was Ranbaxy (who was fully indemnifying Teva) potentially liable for lost profits, but Pfizer had requested that the district court enhance the damages based on a willful infringement theory.

346. In a patent case, if willful infringement is found, that may, under 35 U.S.C. § 284, enhance damages up to three times the damages awarded. To prove willful infringement, Pfizer would have had to establish that (1) Teva and Ranbaxy acted despite an objectively high likelihood that their actions constituted infringement of a valid patent, and (2) the objectively defined risk was either known or so obvious that it should have been known to Teva and Ranbaxy.

347. Given the prior litigation between Pfizer and Teva, and Ranbaxy's knowledge of that litigation, including the various district court rulings, Pfizer was likely to establish that the "at risk" launch of Ranbaxy's generic product constituted willful infringement.[36] In addition, Pfizer argued that conduct Teva and Ranbaxy undertook after the Court entered the preliminary injunction in Accupril II such as "stuff[ing] the distribution channels with infringing product until the injunction was formally entered two days later" and taking no "action to withdraw its enjoined product from the market . . . [and] inform[ing] its distributors/customers that it would not accept any returns" constituted willful infringement of the '450 patent.

[35] *Accupril II*, ECF No. 177 at 10.
[36] *See, e.g.*, *Accupril II*, ECF No. 94 at 15-16.

348. So by early 2008, as to Accupril, Pfizer had Ranbaxy over a very large barrel—exposed to hundreds of millions of dollars in damages from the Accupril II litigation. Escaping from that liability would be of enormous financial value to Ranbaxy.

Release of the *Accupril* liability for a token $1 million payment is a large and unexplained reverse payment from Pfizer to Ranbaxy

349. On its face, Ranbaxy's $1 million token payment to Pfizer to settle the *Accupril II* litigation was so far below fair value that it may fairly be characterized as a fig leaf to hide the true economic realities of the transaction. Ranbaxy's likely exposure for its "at risk" sales of Accupril was so high that Pfizer could leverage Ranbaxy to quit efforts to enter the Lipitor market in a timely manner. The $1 million payment was a pretext to hide *the economic reality that the transaction yielded a massive net payment worth hundreds of millions of dollars to Ranbaxy*.

350. The release of Ranbaxy from hundreds of millions of dollars in likely liability for *Accupril II* for $1 million was not fair value. Having represented to the Court, the public, and its shareholders that it held a claim likely valued at multi-hundred million dollars against Ranbaxy, Pfizer could not give up that claim for a mere $1 million, *unless there was another component to the deal*. That component was Ranbaxy's agreement to delay launching Lipitor until November 30, 2011.

351. Pfizer also gave Ranbaxy the right to market generic Lipitor in at least eleven foreign markets outside the United States. These provisions provided no benefit to United States consumers or to competition in the United States. And these provisions added to the financial inducements provided by Pfizer to Ranbaxy, and were not of a kind that Ranbaxy could ever expect to achieve through success in any litigation of U.S. Lipitor patents. Entry into these markets provided Ranbaxy with billions of dollars in revenues and profits that it would not have

received absent Pfizer's and Ranbaxy's market-allocating agreement to foreclose generic Lipitor competition in the United States.

352. The Ranbaxy Delay Agreement also ostensibly gave Ranbaxy protection from potential infringement liability in connection with the variety of patents that purportedly covered atorvastatin. However, this "consideration" was of little value because Pfizer did not believe there was any such legitimate threat of infringement of such patents.

353. Pfizer's release of Ranbaxy from hundreds of millions of dollars in likely *Accupril II* liability far exceeded any litigation costs (in any or all cases) Pfizer avoided by settling.

In exchange for Pfizer's payment, Ranbaxy agreed to delay its launch of generic Lipitor and to bottleneck later would-be generics

354. In exchange for the massive payments made by Pfizer to Ranbaxy, Ranbaxy agreed (i) to delay its generic entry of Lipitor until November 30, 2011, (ii) not to relinquish or selectively waive its first-to-file 180-day marketing exclusivity in a manner that would permit any other ANDA filer to market a generic version of Lipitor before November 30, 2011 (*i.e.*, create a bottleneck blocking later-filed ANDAs), (iii) not contest the validity of the process patents, and (iv) cease protesting Pfizer's application for reissuance of the '995 Patent.

355. First, Ranbaxy agreed to be enjoined from selling any atorvastatin product in the United States until the end of November of 2011. In other words, at the time of the June 2008 agreement (when there were no patents that could stop Ranbaxy's entry after March of 2010), Ranbaxy agreed not to compete with a generic Lipitor until November of 2011. As part of the Ranbaxy Delay Agreement, Pfizer granted Ranbaxy a license to all patents controlled by Pfizer that were necessary for making atorvastatin calcium, effective only on and after November 30, 2011, for the life of each such Lipitor patent.

356. Second, to ensure that no other generics could enter the market and destroy Pfizer's Lipitor monopoly, Ranbaxy agreed to not relinquish or selectively waive its first-to-file 180-day marketing exclusivity in a manner that would permit any other ANDA filer to market a generic version of Lipitor in the United States before November 30, 2011. This aspect of the Ranbaxy Delay Agreement both bottlenecked regulatory approval for other would-be entrants and barred Ranbaxy from cutting a deal to enable selective entry by one or more a co-ventured generics prior to November of 2011.

357. Third, Ranbaxy agreed to cease protesting Pfizer's application for reissuance of the enantiomer patent (the '995 Patent).

Absent the reverse payment agreement, Ranbaxy would have received FDA ANDA approval for generic Lipitor earlier

358. Ranbaxy's ANDA would have been approved, and Ranbaxy (either on its own, or with a generic partner) would have launched generic Lipitor earlier had there been no unlawful reverse payment (*i.e.*, but for the large reverse payment in the Ranbaxy Delay Agreement). Alternatively, absent Ranbaxy's ability to launch (either at all, or in sufficient commercial quantities to supply the market), Ranbaxy would have selectively waived, or forfeited entirely, its 180-day exclusivity rights in favor of other generic Lipitor ANDA filers.

359. Ranbaxy's atorvastatin calcium ANDA would have received final approval earlier absent the Defendants' anticompetitive conduct. The FDA has policies and procedures in place to prioritize the review of ANDAs, *e.g.*, expediting the review of the first applications for which there are no blocking patents or exclusivities. Regarding the FDA's review of applications for generic Lipitor, the Ranbaxy Delay Agreement blocked all generic applicants, including Ranbaxy, from marketing their products. The FDA was aware that the earliest date Ranbaxy could market generic Lipitor under its agreement with Pfizer was November 30, 2011, and thus

its (and Ranbaxy's) approval efforts focused on that date (not earlier dates). As Ranbaxy maintained its 180-day exclusivity, all subsequent applicants were blocked from marketing generic Lipitor as well, until Ranbaxy's exclusivity was triggered and had elapsed.

360. Furthermore, the FDA was under tremendous pressure, including from Congress, to speed consumer access to generic Lipitor at the earliest possible moment. Ranbaxy was also under tremendous pressure to monetize its biggest asset, *i.e.*, its first-to-file ("FTF") atorvastatin ANDA, at the earliest possible moment, so much so that Ranbaxy paid Teva a large amount of money—in effect an insurance policy—in order to ensure that Ranbaxy was able to launch generic Lipitor at the earliest possible moment.

361. As it turned out, given the existence of the Ranbaxy Delay Agreement, the FDA had no reason to grant final approval before November 30, 2011, and so it did not do so until then. But had the Ranbaxy Delay Agreement permitted an earlier entry date, or had there been no such agreement at all, generic Lipitor could have been, and would have been, marketed earlier than November 30, 2011, because the FDA would have granted final approval earlier and Ranbaxy would have launched earlier.

362. The FDA did not issue its formal written denial of Pfizer's baseless citizen petition until November 30, 2011 for the same reason: the FDA knew from Ranbaxy that the Ranbaxy Delay Agreement prevented Ranbaxy from coming onto the market until November 30, 2011 anyway. Thus, there was no need for the FDA to issue the formal written denial of Pfizer's petition earlier than November 30, 2011, and it was for that reason that the FDA did not do so. This followed common FDA practice. Where approval of the ANDA was tied to a specific, agreed-upon entry date, the FDA would not formally deny a petition relating to bioequivalence issues until the time at which the generic could come to market.

The longstanding FDA policy of prioritizing the review of ANDAs

363. As a matter of procedure and practice, the FDA has long employed methods of prioritizing the review of pending ANDA applications. For example, in 1990, the Division of Generic Drugs within the FDA issued a policy and procedure guide establishing a "first-in, first-reviewed" policy for generic drug applicants. This policy, along with similar guidance for the pharmaceutical industry, has been updated and modified from time to time and is still in place today. One modification that has been instituted over the years is to prioritize the review of the first ANDAs for which there is no blocking patent or exclusivity.

364. The FDA has been experiencing a backlog of pending applications, such that prioritizing ANDA review is more important than ever. Furthermore, as a matter of procedure and practice, in a situation where an ANDA filer will not be able to market a drug until a time far into the future, such as Ranbaxy's generic Lipitor ANDA due to the Ranbaxy Delay Agreement, the FDA shifts assets to other priorities within the Office of Generic Drugs. The FDA prioritizes the review of ANDAs in this way by keeping abreast of the current posture of any litigation that may impact the timing of approval of an ANDA. For instance, as a matter of procedure and practice, upon accepting an ANDA for filing, the FDA expressly requests that the applicant promptly submit a copy of any settlement agreement between the applicant and the patent holder.

The FDA's review of Ranbaxy's ANDA for atorvastatin calcium

365. On June 18, 2008 Ranbaxy publicly announced its agreement with Pfizer, including the news that under the agreement Ranbaxy's launch date was delayed until November 30, 2011. Ranbaxy submitted this information to the FDA shortly thereafter. Ranbaxy also informed the FDA that its proposed generic product was now crystalline atorvastatin calcium, pursuant to a

license from Pfizer. As Ranbaxy no longer intended to market amorphous atorvastatin calcium, the citizen petition was moot.

366. Thus, due to the FDA's longstanding policy of prioritizing the review of ANDAs and the recent pressure of the ANDA backlog, on information and belief, once the FDA learned of the fact that the first generic for Lipitor, *i.e.*, Ranbaxy's generic product, would not be marketed until November 30, 2011, the FDA shifted resources away from Ranbaxy's ANDA and the Pfizer petition and toward other priorities within the FDA until the November 2011 date drew closer.

The tremendous pressure on the FDA to approve generic Lipitor

367. That the FDA was under immense pressure to approve a generic Lipitor product also shows that it would have approved Ranbaxy's ANDA earlier absent the agreed-to date for Ranbaxy's market entry contained in the Delay Agreement. But, since the November 2011 date was set by the Ranbaxy Delay Agreement, the FDA could not speed up Ranbaxy's actual launch, regardless of what efforts the FDA might make.

368. For example, on March 10, 2011 Senate Health, Education, Labor, and Pensions Committee Chairman Tom Harkin, along with Senators Jay Rockefeller, Charles Schumer, Debbie Stabenow, and Sherrod Brown sent a letter to FDA Commissioner Dr. Margaret Hamburg. In the letter the Senators stated, "Given the tremendous savings that access to generic atorvastatin will afford both consumers and the government, we urge you to act now to clarify the relevant regulatory issues in the matter so the public can receive access to a more affordable generic version of Lipitor on the earliest possible date." The "tremendous savings" to consumers and the government would be between "$3.97 billion to $6.7 billion a year upon generic entry,

which equates to $10.9 million to $18.3 million a day." Likewise, the FDA recognized the importance and cost savings of having a generic Lipitor available to consumers.

369. Absent the Ranbaxy Delay Agreement, Ranbaxy would have received ANDA approval earlier.

Absent the reverse payment agreement, Ranbaxy would have launched generic Lipitor earlier.

370. Not only would the FDA's approval of Ranbaxy's ANDA been forthcoming earlier, but absent the reverse payment in the Ranbaxy Delay Agreement, Ranbaxy would have made arrangements to launch an AB-rated generic atorvastatin calcium on or after March 24, 2010.

371. Absent the large payment in the Ranbaxy Delay Agreement and given the enormous profit opportunity generic Lipitor presented, Ranbaxy would have been highly motivated to pursue generic entry much earlier than November 30, 2011. In early 2008 (the time when the Ranbaxy Delay Agreement was executed), at least three alternatives were available to Ranbaxy to effectuate generic entry earlier than November of 2011.

372. First, Ranbaxy and Pfizer could have entered into a Pfizer/Ranbaxy agreement that simply did not have a large, extraneous financial payment to Ranbaxy. In other words, they could have settled pending and potential future Lipitor patent disputes with a negotiated entry date no later than June 28, 2011 (or likely earlier) but without the kind of large and unexplained reverse payment that gives rise to antitrust scrutiny.

373. Each party was motivated to reach some kind of resolution. Pfizer's suit over its Process Patents held no prospect for success. Its efforts to achieve re-issuance of the '995 Patent were, to date, unsuccessful, in no small part due to Ranbaxy's opposition. Even if Pfizer did obtain a re-issued enantiomer patent, Ranbaxy was sure to challenge the patent in the courts. And Pfizer had only recently settled with generic maker Cobalt (which had been pursuing launch of

an atorvastatin product using a sodium rather than calcium salt) by appointing Cobalt as the future, exclusive (even as to Pfizer) seller of an authorized generic version of Lipitor, with a launch date to be timed to coincide with the launch of the first ANDA-approved Lipitor generic (but no later than November of 2011). (If Ranbaxy launched generic Lipitor before November 2011, Pfizer had agreed that Cobalt could launch an authorized generic as well.)

374. Pfizer was motivated to settle. In early 2008 there existed a serious and real threat that Ranbaxy, or Ranbaxy working with one or more ANDA applicant, through a 180-day selective waiver or forfeiture collaboration, might effectuate the launch of generic atorvastatin calcium once the '893 exclusivity expired in March of 2010. Ranbaxy has expressed its willingness to enter at risk with a generic product of other blockbuster drugs, telling one court that "Ranbaxy [] presently intends to manufacture, use, sell and offer to sell drug products for which the ANDA has been submitted once the FDA approves the ANDA"—in other words, Ranbaxy would launch its generic "once the FDA approv[ed]" it and would not need to await final resolution of the patent case. And in other drug situations Ranbaxy had collaborated with other would-be generic entrants to effectuate "at risk" launches.

375. Ranbaxy, too, had strong motivations to settle, even if it could not have its huge *Accupril* liability paid off by Pfizer. The first-to-file status Ranbaxy held for Lipitor was the true pearl in its inventory of ANDA applications; the sooner it launched, the sooner it could monetize that opportunity.

376. A Lipitor patent settlement between Pfizer and Ranbaxy that did not involve a large and extraneous financial payment to Ranbaxy would have focused discussions on the litigation positions (existing and future) of the parties. And the result would have achieved a negotiated generic entry date markedly earlier than November of 2011, and certainly no later than June of

2011. Without the large payoff to Ranbaxy, Ranbaxy's position would have been that an agreed entry date shortly after March of 2010 was in order (as there was no enantiomer patent blocking its entry at the time, and the prospect for re-issuance was dim). In response, Pfizer would have argued for a later entry date, but its weak position would not warrant entry dates into 2011. So absent Pfizer's payments to Ranbaxy, Ranbaxy would not have agreed to delay of its launch of generic Lipitor into late 2011. At a minimum, absent the payment to Ranbaxy, Ranbaxy would not have agreed to delay its launch (or to delay its authorizing another ANDA filer to launch) for as long as it did, and would instead have agreed only to a substantially shorter period of time before which it would enter.

377. A second alternative available to Ranbaxy to effectuate generic entry earlier than November of 2011 was to litigate, win, and then launch. Some of the Lipitor patents had never even been asserted against Ranbaxy, nor would they ever be. The '995 Patent had been declared invalid, and could not be asserted. And Ranbaxy had dispositive arguments against the enantiomer re-issue application. If Ranbaxy continued its opposition, either the PTO would not have issued an enantiomer patent, or Ranbaxy would have prevailed in any legal effort to use a later-issued enantiomer patent as a basis to preclude marketing of a generic Lipitor. After all, Pfizer's re-issue request now eschewed any reliance on the falsified data, and its sole reliance on commercial success was fundamentally flawed. Finally, the process patent litigation was baseless and had been conjured up solely as a vehicle to house a reverse payment settlement.

378. Pfizer has acknowledged the lack of lawful exclusionary power for a significant portion of this time, namely, from June of 2011. In 2005, before the Ranbaxy Delay Agreement existed and before the '995 Patent was declared invalid, Pfizer's former Chairman and CEO stated:

> There are dozens of generic drug manufacturing companies with a red circle around June 28, 2011. That's the day the patent for our anti-cholesterol medication Lipitor expires. . . . Shortly thereafter a number of generic alternatives to Lipitor will be introduced and consumers will have a choice of generic tablets containing atorvastatin calcium[.]

379. Of course, at the time of this statement only the '995 Patent expired in June of 2011. Other patents purportedly covering Lipitor—namely the Unasserted Stablization Formulation Patents, the '156 Patent, and the Process Patents—would expire between 2013 and 2017. If the Unasserted Stabilization Formulation Patents, the Process Patents, and/or the '156 Patent had any hope of legitimately keeping generics off the market, Pfizer's CEO would not have ignored them and the literally tens of billions of dollars they would have conferred on Pfizer. His statement that June 28, 2011 is the key date makes sense only if one recognizes—as Pfizer did—that the Unasserted Stabilization Formulation Patents, the Process Patents, and the '156 Patent could not block generics from entering.

380. Regarding the petition filed by Pfizer in 2005, it would not have delayed final approval of Ranbaxy's ANDA under the scenarios outlined above. First, in light of Ranbaxy's settlement with Pfizer, Ranbaxy switched to a non-amorphous form of atorvastatin. As a result, the FDA concluded that "the issues raised in the [petition] are not pertinent to the Ranbaxy ANDA, as amended, and that this petition need not be responded to prior to the approval of Ranbaxy's ANDA." *See* Comment of Robert L. West, Deputy Director of the Office of Generic Drugs, in the Approval Routing Sheet for Ranbaxy's atorvastatin calcium ANDA, at p. 5. A settlement between Pfizer and Ranbaxy eliminating only the illegal inducements for delayed entry would have given rise to this same situation. Second, in light of the agreed-upon November 30, 2011 entry date, the FDA was not incentivized to rule on the petition any earlier than that, as the potential effects of such a ruling could only affect other ANDA filers. Cognizant of this

potential impact, the FDA wanted to, and did, rule on the petition in such a fashion that did not delay market entry for other ANDA filers.

381. In short, an infringement case against Ranbaxy (or any other ANDA filer), based upon any legitimately-obtained Lipitor patent that expired after March 24, 2010, would have been (and was, with respect to, for example, Pfizer's suit claiming infringement of Pfizer's Process Patents) a failure. As a result, the Ranbaxy Delay Agreement gave Pfizer protection from generic Lipitor competition beyond the lawful limits of its exclusionary power under any Lipitor-related patent. Neither Pfizer nor Ranbaxy subjectively believed there was any legitimate threat of infringement from such patents.

382. A third alternative available to Ranbaxy in early 2008 to effectuate generic entry earlier than November of 2011 was to continue to litigate, but launch its generic Lipitor after March of 2010 without awaiting its likely litigation victories. In 2008, Pfizer's then-existing Lipitor patent portfolio did not put Ranbaxy (or likely any other relevant ANDA filer) in danger of liability for infringement of any legitimately-obtained patent past March of 2010 (the expiry of the '893 Patent). No legitimately-obtained patent posed a reasonable or realistic threat of infringement liability to Ranbaxy (or likely any other relevant ANDA filer) for making or selling generic Lipitor, other than the '893 Patent. And as of the date of the Ranbaxy Delay Agreement, the only means by which Pfizer could have prevented a launch by Ranbaxy of generic Lipitor on or after March 24, 2010 was by obtaining an injunction. But as Pfizer knew in 2008, obtaining such an injunction would have been impossible, because it would have required a showing that Pfizer was likely to succeed on the merits of process patent infringement claims that it could not win.

383. In sum, there were multiple ways and avenues by which Ranbaxy would have launched generic Lipitor before November 2011 but for the Ranbaxy Delay Agreement. Ranbaxy was motivated to monetize its first-to-file 180-day marketing exclusivity, and would have more rapidly pursued its atorvastatin calcium ANDA absent the agreed-to date for Ranbaxy's market entry contained in its reverse payment agreement with Pfizer.

384. The first-to-file generic Lipitor was a tremendous opportunity for Ranbaxy. Despite only being on the market with a generic Lipitor for one month of 2011, atorvastatin calcium was Ranbaxy's largest selling product in 2011. Ranbaxy also achieved sales growth of 17% over the previous year, "mainly on account of revenues from First to File product, Atorvastatin, in the US market in December 2011." These are significant economic benefits that Ranbaxy could have, and would have, realized long earlier had it not accepted the large payment from Pfizer to delay its launch.

385. Following execution of the Ranbaxy Delay Agreement in 2008, Ranbaxy was in no rush to make preparations for a Lipitor generic launch. After all, it would not be doing so for three and a half years. Eventually, however, Ranbaxy did make its preparations, and these activities would have occurred much earlier had Ranbaxy not promised to delay its launch into the end of 2011.

386. For example, Ranbaxy eventually took steps to ensure issues related its good manufacturing practices did not prevent it from being able to market generic Lipitor. In December 2009, for instance, Ranbaxy effectuated a manufacturing site transfer of atorvastatin calcium from its facility in India to Ranbaxy's wholly-owned subsidiary, Ohm Laboratories in New Jersey. So whatever issues Ranbaxy may have been having with FDA regulatory compliance at one or more of its facilities in India did not affect the Ohm facility in New Jersey.

This is borne out by the fact that Ranbaxy ultimately received approval to market generic Lipitor in the U.S. from the Ohm facility in New Jersey.

387. Absent the Defendants' anticompetitive scheme, Ranbaxy could and would have proceeded with a manufacturing site transfer earlier, either to Ohm or to another facility. The Ohm facility had been operational for Ranbaxy for quite some time and was available for a site transfer in the relevant time period at issue here.

388. In fact, at or around the same time Ranbaxy filed its ANDA for atorvastatin calcium, Ranbaxy also filed the first ANDA to market a dosage strength of a drug in the same "statin" family as atorvastatin calcium, simvastatin. As with atorvastatin, Ranbaxy effectuated a manufacturing site transfer for simvastatin from India to the Ohm facility in New Jersey. Ranbaxy received final approval for its simvastatin ANDA on June 23, 2006 and began marketing its first-to-file generic shortly after.

389. Similarly, in the same time period as the atorvastatin calcium filing, Ranbaxy filed the first ANDA with FDA to market donepezil hydrochloride, the active ingredient in the brand drug Aricept. Aricept had approximately $2.6 billion in sales in 2010. Around the time of the atorvastatin calcium site transfer in December 2009, Ranbaxy effectuated a site transfer of donepezil hydrochloride from India to the Ohm facility in New Jersey. On the first day a generic version of Aricept could be marketed, November 26, 2010, Ranbaxy received approval with first-to-file exclusivity to market donepezil hydrochloride. In 2011 donepezil was the second best performing product after atorvastatin calcium.

390. Finally, Ranbaxy could have, and eventually did, co-venture its generic Lipitor efforts in order to facilitate generic entry for Lipitor.

391. Once Ranbaxy made the decision to partner with another company in order to monetize generic Lipitor, it is hardly surprising that Ranbaxy chose Teva. It is well known in the industry that Teva looks to partner with 180-day exclusivity holders given the profit opportunity such exclusivities present. Since Ranbaxy gained approval to market generic Lipitor from its Ohm facility in New Jersey, it never needed the insurance policy the deal with Teva effectively provided. However, Ranbaxy still paid Teva a substantial amount of money in order to be able to monetize its first-to-file atorvastatin calcium ANDA at the earliest possible moment under the Ranbaxy Delay Agreement.

Absent the reverse payment agreement, Pfizer or a co-venture partner would have entered the Lipitor market with an authorized generic earlier

392. Not only would Ranbaxy have entered the market for atorvastatin calcium earlier had there been no large payoff to it as part of the Ranbaxy Delay Agreement, but an authorized generic version of Lipitor would also have entered at or close to the time of Ranbaxy's earlier launch as well.

393. An earlier launch of an authorized generic timed to coincide with Ranbaxy's earlier launch would have occurred either through Pfizer's co-venture arrangements with Cobalt, or through Pfizer's captive generic subsidiary, Greenstone.

394. In April 2008, Cobalt (a generic maker seeking to market a sodium salt version of atorvastatin) and Pfizer agreed to settle patent infringement litigation between them. Cobalt agreed to abandon its challenge to the Lipitor patents, and not to launch its atorvastatin sodium product until at least the expiration date of all patent and regulatory exclusivities related to the '995 Patent on June 28, 2011. In exchange, Pfizer appointed Cobalt as its exclusive (even as to Pfizer) authorized distributor of Pfizer's NDA approved atorvastatin product, which is identical to Pfizer's branded Lipitor, labeled and packaged for distribution into generic drug

channels in the U.S., from the earlier of November 30, 2011 or the date on which any ANDA filer makes generic Lipitor available for sale in the U.S.

395. By appointing Cobalt to be the exclusive distributor of generic Lipitor (under Pfizer's NDA) *with exclusive rights even as to Pfizer*, Pfizer was agreeing to cede all authorized generic sales of Lipitor to Cobalt (*i.e.*, Pfizer was agreeing not to sell an authorized generic version of Lipitor in competition with Cobalt) for five years.

396. As a result, Cobalt and Pfizer were ready, willing and able to launch an authorized generic immediately upon the launch of Ranbaxy's ANDA-approved generic. By delaying the Ranbaxy launch the Ranbaxy Delay Agreement also had the effect of delaying the entry of Pfizer's authorized generic to be launched through Cobalt.

397. And even if the Cobalt agreement did not exist or was not performed, Pfizer nevertheless would have launched an authorized generic immediately upon Ranbaxy's entry. Greenstone is a subsidiary of Pfizer, specializing in the marketing and sale of generic versions of Pfizer's brand-name drugs. Greenstone's business model depends upon Pfizer's drug pipeline, more precisely the time at which Pfizer's drugs will lose exclusivity. For any major brand-name Pfizer drug approaching the end of its exclusivity, the distribution of an authorized generic through Greenstone is likely.

398. Greenstone, however, will not launch any generic product unless and until another company enters the market with its own generic version. Since Greenstone's authorized generic is priced at, or near, the same level as other generics there is no benefit to Pfizer in having Greenstone be the first generic to launch; all of Greenstone's sales would cannibalize the otherwise exclusive branded sales. Once generic entry does occur, usually by a first-to-file ANDA generic company, Greenstone wants to immediately launch its authorized generic.

399. Greenstone itself has no manufacturing capabilities (Pfizer produces the authorized generic versions of its drugs on the same production line as its branded versions). As patent exclusivities approach, and Greenstone's market analysis shows the likelihood of a generic entrant in the market, Greenstone takes steps to have Pfizer manufacture generic versions of the drug.

400. As a result, even if the Cobalt arrangements did not exist, Greenstone would have been ready, willing and able to launch an authorized generic immediately upon the launch of Ranbaxy's ANDA-approved generic. By delaying the Ranbaxy launch the Ranbaxy Delay Agreement also had the effect of delaying the entry of a Greenstone authorized generic.

O. The Operation of the Ranbaxy Delay Agreement

401. Pursuant to the Ranbaxy Delay Agreement, Ranbaxy agreed not to sell its generic version of Lipitor in the United States until November 30, 2011—twenty (20) months after the '893 Patent (and any associated marketing exclusivities) was scheduled to expire, and five (5) months after any re-issued enantiomer patent (the '995 Patent) would expire, if in fact such an enantiomer patent was issued and survived patent challenges. Pfizer and Ranbaxy performed under the Ranbaxy Delay Agreement and successfully delayed multiple efforts by other generics to launch competing products.

Ranbaxy withdraws its challenges to the re-issuance of an enantiomer patent

402. As part of the Ranbaxy Delay Agreement, Ranbaxy agreed not to challenge the validity of any Lipitor patent, including the '995 Patent, which was then the subject of reissuance proceedings. Pursuant to the Ranbaxy Delay Agreement, Ranbaxy dropped its challenge to the re-issuance of the '995 Patent—a challenge which had been successful prior to the date of the Agreement.

403. With Ranbaxy out of Pfizer's way, Pfizer renewed its effort to obtain re-issuance of the enantiomer patent. Pfizer continued to barrage the PTO with information about the commercial success of "Lipitor," treating it as if that were the correct and only relevant issue.

404. Eventually, the PTO relented to Pfizer's barrage of Lipitor materials regarding commercial success.

405. On April 6, 2009, the PTO reissued claims 6, 13, and 14 of the '995 Patent as the '667 Patent. The PTO based its ruling to grant the re-issuance of an enantiomer patent not on the basis of the biological studies and representations made by Warner-Lambert (even though a version of the CSI assay data remains in the specification for the patent), but instead on the basis of Pfizer's arguments that the commercial success of Lipitor shows that the '995 Patent could not have been obvious.

406. The '667 Patent, like its predecessor, would expire (and did expire) on June 28, 2011. (Pursuant to the Ranbaxy Delay Agreement, Ranbaxy could not sell its generic version of Lipitor until November 30, 2011, a full five months after the '667 Patent expired.)

407. The reissue proceedings do, however, confirm what Pfizer had long known: the biologic data submitted as part of the application for the '995 Patent was false, inaccurate, incorrect, and riddled with errors. And by buying off Ranbaxy's opposition to the reissuance of '995 claims, along with a sleight-of-hand with respect in its submissions to the PTO, Pfizer got the PTO to finally allow, albeit incorrectly, several claims of the '995 Patent as the '667 Patent.

The Ranbaxy Delay Agreement created a bottleneck preventing later ANDA filers from entering the market with generic Lipitor

408. The Ranbaxy Delay Agreement also had the purpose and effect of preventing other ANDA filers from launching their own generic versions of Lipitor before Ranbaxy did.

409. As of the 2008 Ranbaxy Delay Agreement, there were only two ways that Ranbaxy's 180-day exclusivity could be triggered. The first trigger event would be when Ranbaxy began selling its generic product—but Pfizer and Ranbaxy had collusively delayed the start of Ranbaxy's generic Lipitor sales, and thus had delayed this trigger date. Other generics would, therefore, remain blocked.

410. The second trigger event would be if other generic companies obtained court decisions that all of the unexpired patents Pfizer had listed in the Orange Book for Lipitor (*i.e.,* the '893, '995, '104, '971, and '156 Patents) were invalid or not infringed. If another ANDA filer were to obtain such court decisions, Ranbaxy's 180-day first-to-file marketing exclusivity would commence running, even if Ranbaxy had not yet begun commercial marketing of its ANDA product by that time, and even if Ranbaxy did not want its exclusivity to commence running.

411. Pfizer did not want generic Lipitor competition before the November 30, 2011 date provided in the Ranbaxy Delay Agreement, and Ranbaxy did not want any involuntary triggering or forfeiture of its anticipated, and enormously valuable, 180-day first-to-file marketing exclusivity.

412. To prevent the involuntary triggering of Ranbaxy's 180-day exclusivity prior to November 30, 2011, Pfizer thwarted the efforts of other generic manufacturers to obtain judgments of invalidity or non-infringement with respect to the '104, '971 and '156 Patents. Pursuant to and in furtherance of the Agreement, Pfizer engaged in a sustained campaign of serial meritless litigation to manipulate the regulatory scheme and thwart the efforts of generic manufacturers to obtain judgments of invalidity and/or non-infringement with respect to the

Lipitor patents, thus preventing the involuntary triggering of Ranbaxy's 180-day first-to-file marketing exclusivity prior to November 30, 2011 and preserving the bottleneck.

Apotex

413. For instance, after it received a Paragraph IV certification in December of 2008 from Apotex, Inc. and Apotex Corporation ("Apotex") as to the '995 Patent, the Unasserted Stabilization Formulation Patents, and the '156 Patent, Pfizer sued Apotex for infringement of only the '995 Patent. Apotex's answer included counterclaims, pursuant to 21 U.S.C. § 355(j)(5)(C), asserting non-infringement and invalidity of the both the '995 Patent (and '667 reissue patent), the Unasserted Stabilization Formulation Patents, and the '156 Patent.

414. As the Apotex trial court recognized: "Apotex's hope is to obtain a decision from this Court that the Unasserted Patents are invalid or are not infringed by Apotex's product, thereby triggering Ranbaxy's exclusivity period. Absent such a court ruling (either in this case or in litigation involving another subsequent ANDA filer), Apotex will not be able to market its generic atorvastatin drug until 180 days after Ranbaxy begins marketing its drug, which, as a result of the settlement agreement between Pfizer and Ranbaxy, will not occur until November 2011 at the earliest."

415. In furtherance of the Ranbaxy Delay Agreement, Pfizer sought dismissal of Apotex's counterclaims, arguing that they were nonjusticiable.

416. Although the Apotex court denied Pfizer's motion to dismiss, the motion had its intended effect: it delayed discovery and litigation for well over a year and, combined with subsequent litigation delay tactics surrounding discovery and summary judgment motions, prevented Apotex from obtaining a judgment of non-infringement and invalidity of the Unasserted Stabilization Formulation Patents and the '156 Patent before November 30, 2011.

Mylan

417. On May 1, 2009, Mylan sent Pfizer a letter providing notice of Mylan's ANDA submission and intent to market a generic version of Lipitor, supplying a Paragraph IV certification as to the Unasserted Stabilization Formulation Patents and the '156 Patent, and offering confidential access to certain portions of Mylan's ANDA. By June 15, 2009, Pfizer had filed an action against Mylan alleging infringement of only the '156 Patent, and seeking a declaratory judgment of infringement of the Process Patents.

418. Mylan filed a motion for leave to file an amended answer containing counterclaims pertaining to the Unasserted Stabilization Formulation Patents, to obtain a declaration of noninfringement and/or invalidity with respect to them. In support of that effort, Mylan sought discovery regarding the Unasserted Stabilization Formulation Patents. Mylan's motion to compel discovery was granted by court order on August 25, 2010.

419. But Pfizer continued to refuse to supply Mylan with the discovery it required. Mylan was forced to file an emergency motion to enforce the court's discovery order.

420. To frustrate Mylan's continued efforts to obtain discovery and thus proceed with its counterclaims pertaining to the Unasserted Stabilization Formulation Patents, Pfizer, on August 30, 2010, hastily covenanted not to sue Mylan on them, hoping to moot Mylan's continued efforts to discover facts that would assist its counterclaims and the court's order of August 25, 2010 compelling that discovery.

421. The court expressed frustration with Pfizer's litigation tactics regarding the Unasserted Stabilization Formulation Patents, and enforced its order requiring Pfizer to supply discovery to Mylan pertaining to them:

> I'm granting Mylan's request. I'm very troubled by the conduct of Pfizer here with respect to this ongoing discovery dispute. The way I see it, if Pfizer wanted

> to provide a covenant not to sue, it was within its authority at any time to provide the covenant not to sue with respect to the formulation patents. For whatever reasoning only known to Pfizer, they waited until August 30th [2010] to give the covenants not to sue, which was perhaps not coincidently shortly after the issuance of the August 25th order granting the defendants' request for discovery * * * That's simply just not how this is supposed to work.

422. Pfizer continued to delay the progress of the case. In a November 20, 2010 letter to the court regarding Dr. Reddy's Laboratories Ltd.'s ("DRL") request to be heard at the *Markman* hearing in the Mylan patent litigation pertaining to the '156 Patent, counsel for Mylan complained about Pfizer's continued dilatory tactics: "Pfizer uses DRL's request to be heard on the '156 patent as another opportunity to attempt to delay the Pfizer-Mylan cases."

423. Mylan also sought to remove Ranbaxy's blocking 180-day exclusivity period by way of a separate action against FDA seeking an order requiring FDA to determine whether or not Ranbaxy was entitled to a 180-day first-to-file marketing exclusivity.

Actavis

424. In August of 2010, Pfizer sued Actavis Group hf, Actavis Inc., Actavis Elizabeth LLC and Actavis Pharma Manufacturing Private Ltd. (collectively "Actavis") after Actavis submitted to the FDA an ANDA seeking approval to market generic Lipitor. Although Actavis had included the Unasserted Stabilization Formulation Patents in its Paragraph IV certification, Pfizer sued Actavis only for infringement of the '156 Patent.

425. In September 2010, Actavis counterclaimed for declaratory judgment of invalidity and non-infringement of the Unasserted Stabilization Formulation Patents. Pfizer moved to dismiss these counterclaims as unripe. In opposing that motion, Actavis argued that "Pfizer's listing of the [Unasserted Stabilization Formulation Patents] in the Orange Book and its refusal to litigate them creates patent uncertainty and indefinitely delays the approval of Actavis' ANDA," and noted that "[e]ven if Pfizer granted Actavis a covenant not to sue on the

[Unasserted Stabilization Formulation Patents], however, it would not address the fact that Actavis is suffering from an indefinite delay in FDA approval of its ANDA and its concurrent inability to enter the market."

426. Actavis also argued that, by virtue of Pfizer's agreement with Ranbaxy and its refusal to litigate the validity and infringement of its Unasserted Stabilization Formulation Patents, "Actavis is being restrained from the free exploitation of non-infringing goods, it is suffering exactly the type of injury-in-fact that is sufficient to establish Article III standing" (internal citations and quotations omitted).

427. Despite their efforts to do so, no ANDA filer was able to circumvent the Ranbaxy Delay Agreement between Pfizer and Ranbaxy by triggering Ranbaxy's 180-day marketing exclusivity prior to November 30, 2011.

The Ranbaxy Delay Agreement operated as an unlawful reverse payment agreement

428. In summary, the Ranbaxy Delay Agreement was unlawful for at least the following reasons: (a) it constituted an illegal market allocation agreement, pursuant to which Pfizer paid substantial monies to its competitor, Ranbaxy, in exchange for Ranbaxy's agreement to allocate the entire United States market for atorvastatin calcium to Pfizer through November 30, 2011; (b) it restricted competition in a manner, and to an extent, that exceeds the exclusionary power and potential of Pfizer's Lipitor patents; and (c) to the extent it purported to settle patent claims against Ranbaxy for infringement of any Lipitor-related patent extending past March 24, 2010, it was (with respect to the Process Patents), or would have been (with respect to the Unasserted Stabilization Formulation Patents, the '156 Patent, the '995 Patent, and '667 Patent), baseless sham litigation that Pfizer and Ranbaxy knew had no realistic chance of prevailing on the merits.

429. There was no cognizable, non-pretextual procompetitive justification for the Ranbaxy Delay Agreement, nor was there for the substantial financial inducement flowing to Ranbaxy under the Agreement. Even if there were some conceivable justification, the Ranbaxy Delay Agreement, and the payments flowing to Ranbaxy under the Agreement, were not reasonably necessary to achieve it.

430. The defendants did not need to resort to payments from Pfizer to Ranbaxy in order to resolve their patent litigation. To the contrary, according to FTC analyses, in 2004 and 2005, a majority of agreements between brand and generic manufactures settling patent disputes contained no anticompetitive payment from the brand to the generic manufacturer. Like the parties to other such agreements identified by the FTC, were it not for the anticompetitive payment from Pfizer to Ranbaxy, if defendants would have entered into an agreement at all, they would have entered into an agreement providing that Pfizer would not compensate Ranbaxy for delay, and that Ranbaxy would enter far earlier than the Ranbaxy Delay Agreement provided.

P. The PTO's Reissuance of the '995 Patent Does Not Absolve Warner-Lambert's Fraudulent Conduct or Otherwise Sanitize the '995 Patent

431. As alleged above, but for Warner-Lambert's fraudulent conduct during the initial prosecution of the '995 Patent, the '995 Patent never would have issued. But for the '995 Patent's additional period of patent protection, at least one generic version of Lipitor would have been available far earlier than it was. The '995 Patent would have never issued initially but for Warner-Lambert's fraud. And without the original issuance of the '995 Patent, there could be no reissuance of it. Without the reissue proceedings, the reissue patent that did emerge from that proceeding, the '667 Patent, would not exist.

432. The PTO based its ruling to grant the reissuance of the '995 Enantiomer Patent not on the basis of the biological studies and the associated representations made by Warner-Lambert

(even though a version of the CSI assay data remains in the specification for the patent), but instead on Pfizer's arguments that the commercial success of Lipitor shows that the '995 Enantiomer Patent could not have been obvious. This argument is patently wrong as a matter of fact and law.

433. First, Lipitor was commercially successful during the 1997-2010 time period, a period during which it enjoyed patent protection under both the '893 Original Lipitor Patent and the '995 Enantiomer Patent. Since the relevant question of obviousness is whether the '995 Patent is obvious when compared to the '893 Patent, the fact that Lipitor, which is covered by both patents, has been commercially successful generally provides no meaningful information as to the distinctions *between* the two patents.

434. Second, when Pfizer boasts of Lipitor's "commercial success," it makes comparisons between Lipitor and other statins, or between Lipitor and the overall growth in the statin market generally. But the relevant issue of obviousness does not involve a comparison of Lipitor to other statins or to growing statin use. Instead, the relevant issue of patent obviousness is whether the invention under the '995 Enantiomer Patent would have been successful as compared to an invention under the '893 Original Lipitor Patent. However, because both the '893 and '995 Patents cover the same product, looking to Lipitor's general success, or to its success as compared to other statins, provides no insight as to whether the '995 Patent is obvious as compared to the earlier '893 Patent. To have any kind of a meaningful "commercial success" information as it relates to whether the '995 Enantiomer Patent was obvious, one must compare an invention under the '995 Patent to a *different* invention under the '893 Patent. There is no invention that fulfills these parameters.

435. Pfizer knew that this argument of looking generally at "Lipitor" (rather than distinguishing attributes of the enantiomer that were surprising and unexpected) was a deception. Pfizer knew that the '893 Patent protected Lipitor from the initial launch of Lipitor through all of the re-issue proceedings. Thus, any showing of success of Lipitor generally would not in any way elucidate why the '995 Patent (which also covered Lipitor) was not obvious over the original '893 compound patent. Indeed, Warner-Lambert, and later Pfizer, repeatedly used the '893 Patent as the patent which would provide protection for Lipitor. Warner-Lambert listed the '893 Patent in the Orange Book, thus protecting Lipitor from generic competition.[37] Shortly after Lipitor was approved by the FDA in late 1996, Warner-Lambert sought, and obtained, a patent extension on the '893 Patent (not the '995 Patent) to make up for the many years that it took to study Lipitor. And Pfizer later brought infringement cases against generic companies arguing that their proposed Lipitor products would infringe the '893 Patent.

436. Put simply, from late 1996 to 2009, Pfizer's commercialization of Lipitor was actively protected by both the original '893 Patent and the '995 Patent, i.e., both patents covered, the commercialized R-trans enantiomer calcium salt formulation. Thus, any arguments raised with the PTO at any time regarding the commercial success of "Lipitor" could not, as a matter of fact or law, elucidate in any way whatsoever whether the '995 Patent was non-obvious over the '893 Patent.[38]

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[37] The use code used for the '893 Patent to cover Lipitor was a "method of inhibiting cholesterol biosynthesis in a patient." Similarly, the use code used for the '995 Patent was defined as a "method of use to inhibit cholesterol synthesis in a human suffering from hypercholesterolemia."

[38] Notably, Pfizer's re-issue application stated that the re-wording of the '995 Patent should be allowed so that the "active ingredient responsible for Lipitor's success [could] be restored and the active ingredient that makes Lipitor work will again be protected by species claims," falsely suggesting that without the allowance Lipitor would be without patent protection. This was a false suggestion because Lipitor's active ingredient was also covered by the original '893 patent as well.

437. In summary, Pfizer and its predecessors obtained, by actual fraud, the '995 Enantiomer Patent. If Pfizer and its predecessors had not committed fraud during the prosecution of the '995 Patent, the PTO would not have issued the '995 Enantiomer Patent and there would not have been any commercial success attributable to the '995 Patent (or other argument as to the validity thereof) on which the Examiner could have relied to reissue the '995 Patent. Had Ranbaxy not settled with Pfizer and abandoned its challenge to the reissue proceedings on these points, the PTO would have never reissued the '995 Patent.

438. Without the '995 Patent, generic manufacturers, many of which filed their ANDAs years ago, would have entered the market far earlier than they did.

VI. EFFECT ON INTERSTATE COMMERCE

439. Defendants' conduct in unlawfully monopolizing and restraining trade and competition in the market for atorvastatin calcium has substantially affected interstate and foreign commerce.

440. During the relevant time period, Pfizer manufactured, promoted, distributed, and sold substantial amounts of branded Lipitor in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Beginning around November 30, 2011, Ranbaxy did the same with respect to generic Lipitor.

441. During the relevant time period, Pfizer transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of branded Lipitor. Beginning around November 30, 2011, Ranbaxy did the same with respect to generic Lipitor.

442. In furtherance of their successful efforts to monopolize and restrain competition in the market for atorvastatin calcium, Defendants employed the United States mail and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

VII. EFFECT ON INTRASTATE COMMERCE

443. During the relevant time period, branded Lipitor, manufactured and sold by Pfizer, was shipped into each state and was sold to or paid for by end-payors. Beginning around November 30, 2011, generic Lipitor, manufactured and sold by Ranbaxy, was shipped into each state and was sold to or paid for by end-payors.

444. During the relevant time period, in connection with the purchase and sale of branded Lipitor, money exchanged hands and business communications and transactions occurred in each state. Beginning around November 30, 2011, in connection with the purchase and sale of generic Lipitor, money exchanged hands and business communications and transactions occurred in each state.

445. Defendants' conduct as set forth in this Complaint had substantial effects on intrastate commerce in that, *inter alia*, retailers within each state were foreclosed from offering cheaper Lipitor and generic atorvastatin calcium to end-payors purchasing inside each respective state, and Defendants entered into an unlawful anticompetitive agreement that affected commerce in each state.

VIII. MONOPOLY POWER AND MARKET DEFINITION

446. At all relevant times, Pfizer had nationwide monopoly power, including in each of the United States, and the District of Columbia, because it had the power to maintain the price of the drug Lipitor at supracompetitive levels without losing substantial sales to other products

prescribed and/or used for the same purposes as Lipitor, with the exception of AB-rated generic versions of Lipitor.

447. A small but significant, non-transitory price increase for Lipitor by Pfizer would not have caused a significant loss of sales to other products prescribed and/or used for the same purposes as Lipitor, with the exception of AB-rated generic versions of Lipitor.

448. Lipitor does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Lipitor.

449. Because of, among other reasons, its use and varying ability to inhibit the production of cholesterol, Lipitor is differentiated from all products other than AB-rated generic versions of Lipitor.

450. Defendants needed to control only Lipitor and its AB-rated generic equivalents, and no other products, in order to maintain the price of Lipitor profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Lipitor would render Pfizer unable to profitably maintain its current prices of Lipitor without losing substantial sales.

451. Pfizer also sold Lipitor at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

452. Defendants have had, and exercised, the power to exclude and restrict competition to Lipitor and AB-rated bioequivalents.

453. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant market is atorvastatin calcium products – *i.e.*, Lipitor (in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products. During the period relevant to this case,

Defendants have been able to profitably maintain the price of Lipitor and/or AB-rated bioequivalents well above competitive levels.

454. Defendants, at all relevant times material, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

455. The relevant geographic market is the United States and its territories.

456. Pfizer's market share in the relevant market was 100% until November 30, 2011, implying a substantial amount of monopoly power.

IX. MARKET EFFECTS

457. On or shortly before November 29, 2011, prior to receiving the FDA's formal, written final approval of its ANDA, Ranbaxy began to ship generic Lipitor. However, Ranbaxy stated that the shipments of generic Lipitor were subject to "quarantine." In other words, until Ranbaxy received the FDA's formal, written final approval of its ANDA, generic Lipitor could not be resold to Plaintiffs' Assignors and members of the Class.

458. By practice, the FDA organizes its priorities around "rate limiters." The FDA knew that the Agreement between Pfizer and Ranbaxy prevented Ranbaxy from selling generic Lipitor until November 30, 2011. The agreement was thus a rate limiter. Accordingly, the FDA purposely waited to issue formal written denial of Pfizer's citizen petition and to issue formal written approval of Ranbaxy's ANDA until November 30, 2011, even though the ANDA was in an approvable condition well before November 30, 2011 and, if not for the Agreement, would have received final FDA approval at an earlier time.

459. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Lipitor from generic competition.

Defendants' actions allowed Pfizer to maintain a monopoly and to exclude competition in the market for Lipitor and its AB-rated generic equivalents, to the detriment of Plaintiff's Assignors and all other members of the Class.

460. Defendants' exclusionary conduct delayed generic competition and unlawfully enabled Pfizer to sell Lipitor without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Lipitor earlier than November 30, 2011, the date on which Ranbaxy first marketed its generic version of the drug. A generic Lipitor would have been on the market much sooner.

461. Pfizer entered into agreements with Medco Health Solutions and several of the nation's largest pharmacy benefit managers ("PBMs") whereby the price of brand name Lipitor would—and did—effectively decrease upon the entrance of generic competition. In some cases, the Pfizer-PBM agreements were intended to function as, and did in fact function as, de facto group boycotts of the generic product at the retail level.

462. Pfizer, acting alone and/or in concert with Ranbaxy, willfully and unlawfully maintained its monopoly power and unlawfully conspired in restraint of trade by engaging in a scheme to exclude competition that discouraged, rather than encouraged, competition on the merits. This scheme was designed for the anticompetitive purpose of forestalling generic competition and was carried out with the anticompetitive effect of maintaining supracompetitive prices for the relevant product. Pfizer implemented its scheme by, *inter alia*, manipulating the prosecution of the '995 Patent, manipulating the reissuance process for the '995 Patent, prosecuting serial sham patent infringement litigation, filing a sham citizen petition, settling on terms outside the scope of the patent to divide and allocate markets, entering into anticompetitive

reverse payment agreements without necessary procompetitive justifications, and abusing the Hatch-Waxman framework, in concert with Ranbaxy, to serve its anticompetitive goals.

463. The generic manufacturers seeking to sell generic Lipitor had extensive experience, capability, and expertise in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products. These generic manufacturers had taken affirmative steps to enter the market, including, without limitation, filing ANDAs with the FDA, and they were otherwise prepared and planned to enter the market.

464. Defendants' illegal acts, which delayed introduction into the U.S. marketplace of generic versions of Lipitor, have caused Plaintiff's Assignors and the Class to pay more than they would have paid for atorvastatin calcium products absent Defendants' illegal conduct.

465. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") branded counterpart to which they are AB-rated. As a result, upon generic entry, end-payors rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand name drug loses even more of its market share to the generic versions of the drug. This price competition enables all purchasers of the drugs to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

466. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, Plaintiffs' Assignors and the Class would have paid less

for atorvastatin calcium by (a) substituting purchases of less-expensive AB-rated generic Lipitor for their purchases of more-expensive branded Lipitor, (b) receiving discounts on their remaining branded Lipitor purchases, and (c) purchasing generic Lipitor at lower prices sooner.

467. Defendants' unlawful conduct had substantial and significant intrastate effects in each state because, *inter alia*, Lipitor and AB-rated generic Lipitor were sold to consumers and third-party payors in each state at higher prices than would have existed absent the unlawful conduct, and Defendants entered into an unlawful agreement that affected commerce, product availability, and competition in each state.

468. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Lipitor.

469. Thus, Defendants' unlawful conduct deprived Plaintiffs' Assignors and the Class of the benefits of competition that the antitrust laws were designed to ensure.

X. ANTITRUST IMPACT

469. During the relevant period, Plaintiffs' Assignors and members of the Class purchased substantial amounts of Lipitor indirectly from Defendants and/or purchased substantial amounts of AB-rated Lipitor bioequivalent generics indirectly from Defendants or others.

470. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their atorvastatin calcium requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Lipitor was artificially inflated by Defendants' illegal conduct, (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Lipitor sooner, and/or (3) the price of AB-rated Lipitor generic atorvastatin calcium was artificially inflated by Defendants' illegal

conduct. The supracompetitive prices were paid at the point of sale, which is where Plaintiffs' Assignors and the Class suffered antitrust impact.

471. As a consequence, Plaintiffs' Assignors and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charge passed through the chain of distribution to end payors such as Plaintiff's Assignors and members of the Class.

472. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." Professor Hovenkamp also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

473. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of Lipitor and AB-rated generic Lipitor to Plaintiff's Assignors and the Class of end-payors defined herein.

474. Pfizer's anticompetitive actions enabled it to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions individually and with Ranbaxy.

475. The prices were inflated as a direct and foreseeable result of Pfizer's anticompetitive conduct individually and with Ranbaxy.

476. The inflated prices the Class paid are traceable to, and the foreseeable result of, the overcharges by Pfizer and Ranbaxy.

XI. CLASS ACTION ALLEGATIONS

477. Plaintiffs' Assignors, on behalf of themselves and all proposed Indirect-Payer Class members, seek injunctive and equitable relief and damages, measured as overcharges, trebled, against the Defendants.

478. Plaintiffs' Assignors bring this action on behalf of themselves and, under Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), as representative of an Indirect-Payer Class defined as:

> [a]ll persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Lipitor and/or its AB-rated generic equivalents in Arizona, California, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, West Virginia, Wisconsin, and the District of Columbia, in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class"), other than for resale, during the period March 24, 2010 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Lipitor or its generic equivalent if they purchased, paid and/or reimbursed some or all of the purchase price.

479. The following persons or entities are excluded from the proposed class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All persons or entities who purchased Lipitor or its AB-rated generic equivalent only for purposes of resale or directly from Defendants or their affiliates;

c. Fully insured health plans (i.e., Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

d. State and local governments to the extent their claims may be asserted under applicable state law only by the state Attorney General, or are otherwise prohibited by applicable law from being asserted by private counsel on a contingent fee basis;

e. Pharmacy benefit managers; and

f. The judges in this case and any members of their immediate families.

480. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe that the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

481. Plaintiffs' Assignor's claims are typical of the claims of the members of the Class. Plaintiff's Assignors and all members of the Class were damaged by the same wrongful conduct of Defendants, i.e., they paid artificially inflated prices for atorvastatin calcium and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Lipitor as a result of Defendants' wrongful conduct.

482. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the Class.

483. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

484. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

485. Questions of law and fact common to the Class include:

a. whether Defendants willfully obtained and/or maintained monopoly power over Lipitor and its generic equivalents;

b. whether Warner-Lambert improperly listed the '995 Patent in the Orange Book;

c. whether Ranbaxy entered into a contract, combination, and/or conspiracy with Pfizer to restrain trade and, if so, whether it should be evaluated under the "rule of reason" standard;

d. whether Pfizer and Ranbaxy unlawfully excluded competitors and/or potential competitors from the market for atorvastatin calcium, *i.e.*, Lipitor and its AB-rated generic bioequivalents (including an authorized generic);

e. whether the Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States with generic versions of Lipitor;

f. whether the Defendants specifically intended to establish or maintain monopoly power over atorvastatin calcium by delaying generic competition;

g. whether the law requires definition of a relevant market when direct proof of market power is available, and if so, the definition of the relevant market;

h. whether there are pro-competitive ends furthered by Defendants' conduct that could not be furthered via methods with less restriction on competition;

i. whether, and to what extent, the Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to the Plaintiff' Assignors and the members of the proposed Class; and

j. the quantum of aggregate overcharge damages to the proposed Class.

486. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

487. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
For Monopolization Under State Law

(Asserted Against Pfizer)

488. Plaintiffs' incorporate by reference the preceding allegations.

489. As described above, from at least July 21, 1987 until November 30, 2011, Pfizer possessed monopoly power nationwide and in each of the United States in the market for atorvastatin calcium products. No other manufacturer sold a competing version of Lipitor before November 30, 2011.

490. Pfizer willfully and unlawfully acquired and maintained its monopoly power in the atorvastatin calcium market through at least November 30, 2011 by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

491. Pfizer knowingly and intentionally engaged in an anticompetitive scheme to monopolize the atorvastatin calcium products (*i.e.*, Lipitor in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products market, as described above. Pfizer accomplished this scheme by, inter alia, (i) fraudulently obtaining the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing serial sham infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) filing a sham citizen petition, (v) fraudulently obtaining reissuance of the '995 Patent, (vi) unlawfully agreeing with Ranbaxy to divide a

market and delay price reductions for Lipitor, and (vii) otherwise engaging in an overarching scheme to unlawfully monopolize and conspire to monopolize the market for atorvastatin calcium.

492. The goal, purpose, and effect of Pfizer's scheme was to prevent and delay the sale of atorvastatin calcium products in the United States at prices significantly below Pfizer's prices for Lipitor, thereby effectively preventing the average market price of atorvastatin calcium products from declining dramatically.

493. The goal, purpose and effect of Pfizer's scheme was also to maintain and extend its monopoly power with respect to atorvastatin calcium products. Pfizer's illegal scheme allowed Pfizer to continue charging supracompetitive prices for atorvastatin calcium products, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

494. Plaintiffs' Assignors and members of the Class purchased substantial amounts of Lipitor and/or AB-rated generic equivalents indirectly from Pfizer and/or other manufacturers.

495. Pfizer knowingly and intentionally engaged in sham litigation against potential manufacturers of AB-rated generic equivalents of Lipitor. Pfizer repeatedly asserted that the generic Lipitor formulations of its competitors infringed its patents, despite knowing that the Lipitor patents were fraudulently procured, invalid, non-infringed, and/or unenforceable. Pfizer filed these sham lawsuits for purposes of using a governmental process as an anticompetitive weapon to keep AB-rated generic equivalents off the market.

496. Pfizer also knowingly and intentionally engaged in a second sham litigation against Ranbaxy when it raised claims regarding the Process Patents (which had been rejected by a Delaware district court in the earlier litigation) in order to provide cover for a "settlement" agreement that extended Pfizer's atorvastatin calcium monopoly and provided for global market

allocation. Pfizer knew at the time it filed the second sham lawsuit that it had no realistic likelihood of success; therefore, Pfizer knew that no reasonable pharmaceutical manufacturer in its position would have believed it had a reasonable chance of succeeding on the merits.

497. As a result of Defendants' illegal conduct, Plaintiffs' Assignors and members of the Class were compelled to pay, and did pay, more than they would have paid for their atorvastatin calcium requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Lipitor sooner than they did, and prices for atorvastatin calcium products would have been lower, sooner.

498. Had manufacturers of generic atorvastatin calcium products entered the market and lawfully competed with Pfizer in a timely fashion, Plaintiffs' Assignors and other members of the Class would have substituted lower-priced generic atorvastatin calcium products for the higher-priced brand-name Lipitor for some or all of their atorvastatin calcium products requirements, and/or would have paid lower net prices on their remaining Lipitor and/or AB-rated bioequivalent purchases.

499. By engaging in the foregoing conduct, Pfizer violated the following state antitrust laws:

a. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Arizona by members of the Class.

b. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in California by members of the Class.

c. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Florida by members of the Class.

e. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Hawaii Rev. Stat. 480-1, *et seq.* with respect to purchases of Lipitor and AB-rated bioequivalents in Hawaii by members of the Class.

f. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq.*), with respect to purchases of Lipitor and AB-rated bioequivalents in Illinois by members of the Class.

g. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Iowa by members of the Class.

h. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Kansas Stat. Ann. § 50-161 (b) *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Kansas by members of the Class.

i. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Maine by members of the Class.

j. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Md. Com'l Law Code Ann. § 11-204(a), *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Maryland by members of the Class.

k. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Massachusetts by members of the Class.

l. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Michigan by members of the Class.

m. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.,* with respect to purchases of Lipitor and AB-rated bioequivalents in Minnesota by members of the Class.

n. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Mississippi by members of the Class.

o. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Mont. Code § 30-14-103, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Montana by members of the Class.

p. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nebraska by members of the Class.

q. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nevada by members of the Class.

r. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Hampshire by members of the Class.

s. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Mexico by members of the Class.

t. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New York by members of the Class.

u. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Carolina by members of the Class.

v. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Dakota by members of the Class.

w. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Or. Rev. Stat. § 646.730, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Oregon by members of the Class.

x. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Rhode Island by members of the Class.

y. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in South Dakota by members of the Class.

z. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Tennessee by members of the Class.

aa. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Utah by members of the Class. Members of the Class include citizens or residents of Utah.

bb. Pfizer intentionally and wrongfully maintained monopoly power in the relevant markets in violation of W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in West Virginia by members of the Class.

cc. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Wisconsin by members of the Class.

500. Plaintiff's Assignors and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic atorvastatin calcium products, sooner, and (2) paying higher prices for atorvastatin calcium products than

they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

501. Plaintiff's Assignors and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

SECOND CLAIM FOR RELIEF
For Conspiracy to Monopolize Under State Law

(Asserted Against All Defendants)

502. Plaintiff's Assignors incorporate by reference the preceding allegations.

503. As described above, from at least July 21, 1987 until November 30, 2011, Pfizer possessed monopoly power in the market for atorvastatin calcium products. No other manufacturer sold a competing version of Lipitor before November 30, 2011.

504. Defendants willfully and unlawfully engaged in a continuing illegal conspiracy to monopolize the atorvastatin calcium market through at least November 30, 2011 by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

505. Defendants knowingly and intentionally conspired to monopolize the atorvastatin calcium products (*i.e.*, Lipitor in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products market, as described above. Defendants accomplished this scheme by, *inter alia*, (i) fraudulently obtaining the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing serial sham infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) filing a sham citizen petition, (v) fraudulently obtaining reissuance of the '995 Patent, (vi) unlawfully agreeing to divide a market and delay price reductions and

generic competition for Lipitor, and (vii) otherwise conspiring to unlawfully monopolize and conspire to monopolize the market for atorvastatin calcium.

506. The goal, purpose and effect of Defendants' scheme was to prevent and delay the sale of atorvastatin calcium products in the United States at prices significantly below Pfizer's prices for Lipitor, thereby effectively preventing the average market price of atorvastatin calcium products from declining dramatically.

507. The goal, purpose, and effect of Defendants' scheme was also to maintain and extend Pfizer's monopoly power with respect to atorvastatin calcium products. Defendants' illegal scheme allowed Pfizer to continue charging supracompetitive prices for atorvastatin calcium products, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Defendants' scheme allowed Ranbaxy to reap the benefits of reduced generic competition in the United States and premature access to foreign markets.

508. Plaintiff's Assignors and members of the Class purchased substantial amounts of Lipitor and/or AB-rated generic equivalents indirectly from Defendants and/or other manufacturers.

509. The agreements between Pfizer and Ranbaxy are overt acts between separate economic entities—actual and potential competitors—and are illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that the agreements and conspiracy to monopolize are a violation of state antitrust law under a "quick look" or "rule of reason" analysis.

510. Defendants knowingly and intentionally engaged in sham litigation involving claims regarding the Process Patents (which had been rejected by a Delaware district court in earlier litigation) that Defendants knew, or should have known, were objectively baseless, in

order to provide cover for an anticompetitive "settlement" agreement that extended the atorvastatin calcium monopoly and provided for global market allocation.

511. Defendants knew at the time Pfizer filed the second sham lawsuit that Pfizer had no realistic likelihood of success; therefore, Defendants knew that no reasonable pharmaceutical manufacturer in Pfizer's position would have believed it had a reasonable chance of succeeding on the merits. Ranbaxy knew, or should have known, that it was at no risk in the second litigation.

512. As a result of Defendants' illegal conduct, Plaintiff's Assignors and members of the Class were compelled to pay, and did pay, more than they would have paid for their atorvastatin calcium requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Lipitor sooner than they did, and prices for atorvastatin calcium products would have been lower, sooner.

513. Had manufacturers of generic atorvastatin calcium products entered the market and lawfully competed with Defendants in a timely fashion, Plaintiff's Assignors and other members of the Class would have substituted lower-priced generic atorvastatin calcium products for the higher-priced brand-name Lipitor for some or all of their atorvastatin calcium products requirements, and/or would have paid lower net prices on their remaining Lipitor and AB-rated bioequivalent purchases.

514. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Lipitor well before November 30, 2011, and they would have been able to market such versions more successfully.

515. By engaging in the foregoing conduct, Defendants violated the following state antitrust laws:

a. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Arizona by members of the Class.

b. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700 and 17200, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in California by members of the Class.

c. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

e. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Hawaii Rev. Stat. 480-1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Hawaii by members of the Class.

f. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq.*), with respect to purchases of Lipitor and AB-rated bioequivalents in Illinois by members of the Class.

g. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Iowa Code §§ 535.5, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Iowa by members of the Class.

h. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Kansas by members of the Class.

i. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Maine by members of the Class.

j. Defendants intentionally and wrongfully engaged in conspiracy to monopolize the relevant market in violation of Md. Com'l Law Code Ann. § 11-204(a), et seq., with respect to purchases of Lipitor and AB-rated bioequivalents in Maryland by members of the Class.

k. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Massachusetts by members of the Class.

l. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Michigan by members of the Class.

m. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et*

seq., with respect to purchases of Lipitor and AB-rated bioequivalents in Minnesota by members of the Class.

n. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Mississippi by members of the Class.

o. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mont. Code § 30-14-103, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Montana by members of the Class.

p. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nebraska by members of the Class.

q. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nevada by members of the Class.

r. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Hampshire by members of the Class.

s. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Mexico by members of the Class.

t. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New York by members of the Class.

u. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Carolina by members of the Class.

v. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Dakota by members of the Class.

w. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Or. Rev. Stat. § 646.730, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Oregon by members of the Class.

x. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Rhode Island by members of the Class.

y. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in South Dakota by members of the Class.

z. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Tennessee by members of the Class.

aa. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Utah Code Ann. §§ 76-10-911, et seq., with respect to purchases of Lipitor and AB-rated bioequivalents in Utah by members of the Class. Member of the Class include citizens or residents of Utah.

bb. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq*., with respect to purchases of Lipitor and AB-rated bioequivalents in West Virginia by members of the Class.

cc. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Wisconsin by members of the Class.

516. Plaintiff's Assignors and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic atorvastatin calcium products, sooner, and (2) paying higher prices for atorvastatin calcium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

517. Plaintiff's Assignors and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

THIRD CLAIM FOR RELIEF
Combination and Conspiracy in Restraint of Trade

(Asserted Against All Defendants)

518. Plaintiff's Assignors incorporate by reference the preceding and succeeding paragraphs as though fully set forth herein.

519. This claim is pled against all Defendants.

520. Defendants willfully and unlawfully engaged in a continuing illegal contract, combination, and conspiracy to restrain trade in the atorvastatin calcium market by engaging in an anticompetitive scheme to keep generic equivalents from the market and to allocate the market between horizontal competitors.

521. Defendants accomplished this scheme by, *inter alia*, (i) obtaining by actual fraud the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) filing a sham citizen petition, (v) fraudulently obtaining reissuance of the '995 Patent, (vi) unlawfully agreeing to divide the market and delay price reductions and generic competition for Lipitor in the United States, and (vii) entering into anticompetitive sham litigation and anticompetitive sham litigation settlements to cover the terms of the agreement allocating the market for atorvastatin calcium in the United States.

522. Defendants knowingly and intentionally engaged in sham litigation regarding process patent claims (that had been rejected by a Delaware district court in earlier litigation) that Defendants knew, or should have known, were objectively baseless in order to provide cover for an anticompetitive "settlement" agreement, outside the scope of the relevant patents, which divided the relevant market between horizontal competitors.

523. The agreements between Defendants are horizontal market allocation and price fixing agreements between actual or potential competitors and are illegal per se under state antitrust laws. Alternatively, this Complaint alleges that these agreements are an unreasonable

restraint of trade, in violation of state antitrust law, under a "quick look" or "rule of reason" analysis.

524. Alternatively, Pfizer's agreements, including its agreement with Ranbaxy, are presumptively anticompetitive reverse payment settlements, subject to "quick look" rule of reason scrutiny, because Pfizer provided substantial consideration in exchange for each generic manufacturer's agreement to delay market entrance.

525. Defendants knew at the time Pfizer filed this sham suit that Pfizer had no realistic likelihood of success; therefore, Defendants knew that no reasonable pharmaceutical manufacturer in Pfizer's position would have believed it had a reasonable chance of succeeding on the merits. Ranbaxy knew, or should have known, that it was at no risk in the second litigation.

526. Through that Agreement, Ranbaxy and Pfizer joined in an anticompetitive scheme as co-conspirators. The Ranbaxy Delay Agreement is and was a contract, combination and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to: (a) allocate all sales of atorvastatin calcium in the United States to the Pfizer defendants until November 30, 2011; (b) prevent the sale of any generic version of atorvastatin calcium in the United States until November 30, 2011; and (c) fix the price at which the Plaintiff's Assignors and all members of the proposed Class would pay for atorvastatin calcium.

527. Under the Defendants' reverse payment agreement, Pfizer paid Ranbaxy financial inducements through large and unexplained payments that vastly exceed the cost of avoided litigation and are not otherwise explained by the value of any services provided by Ranbaxy to Pfizer (other than Ranbaxy's agreement to delay launching its generic Lipitor). There are no

valid, non-pretextual procompetitive business justifications for the Ranbaxy Delay Agreement, nor for the payments to Ranbaxy under the Agreement. Even if there were some conceivable justification, the Ranbaxy Delay Agreement, and the payments flowing to Ranbaxy under the Agreement, were not reasonably necessary to achieve it.

528. In exchange for these payments, Ranbaxy agreed to, and did, delay introduction of its generic Lipitor in the United States.

529. The anticompetitive consequences of Defendants' reverse payment agreement are sufficiently great and sufficiently unrelated to the settlement of the underlying patent dispute, to amount to an unlawful reverse payment agreement, as evidenced by, *inter alia*, the following:

a. Pfizer agreed to pay hundreds of millions of dollars to Ranbaxy through the various arrangements provided for in the agreement, including the enormous market allocation agreement pursuant to which Ranbaxy was permitted to market generic Lipitor in at least eleven foreign markets.

b. Pfizer also agreed to dismiss its action in the District of New Jersey regarding Ranbaxy's at-risk launch of a generic version of Pfizer's product Accupril, for just $1 million, thereby dismissing hundreds of millions of dollars in likely damages against Ranbaxy in connection with a drug other than that which was at issue in the underlying patent litigation;

c. the agreement with Ranbaxy created a bottleneck that prevented and delayed generic entry by other generic manufacturers;

d. absent the agreement, one or more of the generic ANDA filers could have entered the market prior to November 30, 2011; and

e. there is and was no countervailing pro-competitive benefits from the agreement.

530. The goal, purpose, and effect of Defendants' scheme was to prevent and delay the sale of atorvastatin calcium products in the United States at prices significantly below Pfizer's prices for Lipitor, thereby effectively preventing the average market price of atorvastatin calcium products from declining dramatically.

531. The goal, purpose and effect of Defendants' scheme was also to maintain and extend Pfizer's monopoly power with respect to atorvastatin calcium products. The illegal scheme allowed Pfizer to continue charging supracompetitive prices for atorvastatin calcium products, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

532. Plaintiff's Assignors and members of the Class purchased substantial amounts of Lipitor and/or AB-rated generic equivalents indirectly from Pfizer and/or other manufacturers.

533. As a result of Defendants' illegal conduct, Plaintiff's Assignors and members of the Class were compelled to pay, and did pay, more than they would have paid for their atorvastatin calcium requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Lipitor sooner than they did, and prices for atorvastatin calcium products would have been lower, sooner.

534. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of the following state antitrust laws:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 16700 and 17200, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in California by members of the Class.

c. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Florida by members of the Class.

e. Hawaii Revised Statutes Annotated § 480-1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Hawaii by members of the Class.

f. Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq.*), with respect to purchases of Lipitor and AB-rated bioequivalents in Illinois by members of the Class.

g. Iowa Code § 553.4, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Iowa by members of the Class.

h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Kansas by members of the Class.

i. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Maine by members of the Class.

j. Md. Com'l Law Code Ann. § 11-204(a), *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Maryland by members of the Class.

k. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Massachusetts by members of the Class.

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Michigan by members of the Class.

m. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Minnesota by members of the Class.

n. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Mississippi by members of the Class.

o. Mont. Code § 30-14-201, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Montana by members of the Class.

p. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nebraska by members of the Class.

q. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nevada by members of the Class.

r. N.H. Revised Statutes § 356:1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Hampshire by members of the Class.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Mexico by members of the Class.

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New York by members of the Class.

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Carolina by members of the Class.

v. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Dakota by members of the Class.

w. Or. Rev. Stat. § 646.725, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Oregon by members of the Class.

x. R.I. Gen. Laws § 6-36-4, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Rhode Island by members of the Class.

y. S.D. Codified Laws Ann. §§ 37-1-3.1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in South Dakota by members of the Class.

z. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Tennessee by members of the Class.

aa. Utah Code Annotated § 76-10-3103, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Utah by members of the Class. Member of the Class include citizens or residents of Utah.

bb. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in West Virginia by members of the Class.

cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Wisconsin by members of the Class.

535. Plaintiff's Assignors and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic atorvastatin calcium products sooner, and (2) paying higher prices for atorvastatin calcium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

536. Plaintiff's Assignors and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violation of the aforementioned statutes.

FOURTH CLAIM FOR RELIEF
Unfair or Deceptive Trade Practices

(Asserted Against All Defendants)

537. Plaintiffs' Assignors repeats the allegations contained in the foregoing paragraphs as if fully set forth herein.

538. Defendants engaged in unfair competition, and/or unfair/unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair and/or unconscionable acts or practices, Plaintiffs' Assignors and class members were deprived of the opportunity to purchase a less expensive AB-rated bioequivalents and forced to pay higher prices.

a. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*

b. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*

c. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Haw. Rev. Stat. §§ 480, *et seq.*

d. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505.1, *et seq.*

e. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*

f. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*, in that the actions and transactions alleged herein occurred primarily and substantially within Massachusetts, with thousands of end-payors paying substantially higher prices for Lipitor and AB-rated bioequivalents.

g. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Mont. Code Ann. §§ 30-14-101, *et seq.*

h. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Neb. Rev. Stat. §§ 59-1601, *et seq.*

i. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Nev. Rev. Stat. §§ 598.0903, *et seq.*

j. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*

k. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*

l. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.* To the extent New York law so requires, Plaintiff's Assignors hereby forgo any minimum or punitive damages in order to preserve the right of New York Class members to recover actual damages by way of a class action.

m. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1, *et seq.*

n. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of R.I. Gen. Law § 6-13.1-1, *et seq.*

o. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Tenn. Code Ann. §§ 47-18-101, *et seq.*

p. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Utah Code Ann. §§ 13-11-1, *et seq.*

q. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*

539. Plaintiffs' Assignors and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair/unconscionable and/or deceptive acts or practices alleged in this Count. Their injury consists of paying higher prices for Lipitor and/or AB-rated generic bioequivalents than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

XIII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs' Assignors, on behalf of themselves and the Class, demand judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiff representative of the Class;

B. Declare that the conduct alleged herein is in violation of the statutes set forth above;

C. Enter joint and several judgments against Defendants in favor of Plaintiffs' Assignors and the Class;

D. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

E. Award Plaintiffs' Assignors and the Class their costs of suit, including reasonable attorneys' fees and experts' fees as provided by law; and

F. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

XIV. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiffs' Assignors, on behalf of themselves and the proposed class demand a trial by jury on all issues so triable.

DATED this 13th day of September, 2018. Respectfully submitted,

NAPOLI SHKOLNIK PLLC

/s/ Louise R. Caro
Louise R. Caro, Esq.
Florida Bar No.: 633380
lcaro@napolilaw.com
2665 South Bayshore Drive, Suite 220
Coconut Grove, Florida 33133
Telephone (786) 837-5442
Facsimile (786) 800-3901

AND

THE FERRARO LAW FIRM

/s/ James L. Ferraro
James L. Ferraro, Esq.
Florida Bar No.: 381659
jlf@ferrarolaw.com
Janpaul Portal, Esq.
Florida Bar No.: 0567264
jpp@ferrarolaw.com
James L. Ferraro, Jr., Esq.
Florida Bar No.: 107494
jjr@ferrarolaw.com
Brickell World Plaza
600 Brickell Avenue, 38th Floor
Miami, Florida 33131
Telephone (305) 375-0111
Facsimile (305) 379-6222

APPENDIX

Assignments to Plaintiffs

A1. On May 3, 2016, Preferred Medical Plan, Inc. entered into an assignment with MSP Recovery LLC. Said assignment included the following language "[c]lient hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims",[] as also specified in Section 1.1." The assignment contract was executed by individuals of majority, of sound mind, and with legal authority to bind the respective parties. The assignment was entered under Florida law. On Augst 8, 2016, MSP Recovery, LLC entered into an assignment with MAO-MSO Recovery II LLC, Series PMPI, irrevocably assigning its right to recover payments as assigned from Preferred Medical Plan, Inc. Said assignment included the following language "[a]ssignor, hereby irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and is successors and assigns, all of Assignor's right, title, ownership and interest in and to all Assigned Claims…whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the Assigned Claims, and all rights and claims against primary payers and/or third parties that may be liable to Assignor arising from or relating to the Assigned Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims." This second assignment contract was executed by individuals of majority, of sound mind, and with legal authority to bind the respective parties. This second assignment was entered under New York law. Consideration was given between each party in executing these assignments.

A2. On May 12, 2017, SummaCare, Inc. entered into an assignment with MSP Recovery, LLC. Said assignment included the following language "[c]lient hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims"..." The assignment contract was executed by individuals of majority, of sound mind, and with legal authority to bind the respective parties. The assignment was entered under Ohio law. On June 12, 2017, MSP Recovery, LLC entered into an assignment with MSP Recovery Claims, Series LLC, irrevocably assigning its right to recover payments as assigned from SummaCare, Inc. Said assignment included the following language "Assignor,…irrevocably assigns, sells, transfers, conveys, sets over and Delivers to Assignee and its successors and assigns, any and all of Assignors right, title ownership and interest in and to the "Assigned Claims", "Claims', ["][sic]Assigned Assets" and "Assigned Documents" ….whether based in contract, tort, statutory right, and any and all rights (including but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party pursuant to the Agreement, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/r third parties that may be liable to Client arising from or relating to the Claims and all information relating thereto. This second assignment contract was executed by individuals of majority, of sound mind, and with legal authority to bind the respective parties. This second assignment was entered under Delaware law. Consideration was given between each party in executing these assignments.

A3. On December 16, 2014, Interamerican Medical Center Group, LLC (IMC)

entered into an assignment with MSP Recovery, LLC. Said assignment included the following language "[c]lient appoints, directs, and, otherwise, irrevocably assigns all of Client's rights as it pertains to the rights pursuant to any plan, State or Federal statute(s) whatsoever directly and/or indirectly for any of its members and/or plan participants, and/or its rights pursuant to any agreement…." The assignment contract was executed by individuals of majority, of sound mind, and with legal authority to bind the respective parties. The assignment was entered under Florida law. On 2/20/2015, MSP Recovery, LLC entered into an assignment with MSPA Claims 1, LLC, irrevocably assigning its right to recover payments as assigned from Interamerican Medical Center Group, LLC (IMC)." Said assignment included the following language "[a]ssignor hereby irrevocably assigns, transfers, conveys, sets over, and delivers to Assignee or its assigns any and all of Assignor's right, title, ownership and interest in and to all rights and entitlements, that Assignor has, may have had, or has asserted against third parties arising from or relating to the Claims." This second assignment contract was executed by individuals of majority, of sound mind, and with legal authority to bind the respective parties. This second assignment was entered under Florida law.